LICENSING GUIDE

A Guide for Preparation of Applications

for

Medical Programs

South Carolina Department of Health
and Environmental Control

Bureau of Radiological Health

Division of Radioactive Material

Licensing and Compliance

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A GUIDE FOR PREPARATION OF APPLICATIONS FOR

MEDICAL PROGRAMS

1. INTRODUCTION

1.1 GENERAL

The South Carolina Department of Health and Environmental Control regulates the intentional internal or external administration of radioactive material, or the radiation therefrom, to human beings. This type of use is called medical use, and a specific license is required. The regulations governing medical use are contained in Department Regulation 61-63, Radioactive Materials (Title A) entitled Part IV – Medical Use of Radioactive Material.

The Department usually issues a single radioactive material license to cover an entire radioisotope program except teletherapy, nuclear-powered pacemakers, and irradiators. Separate licenses are not normally issued to different departments of a hospital or to individuals employed by a hospital. A license applicant should carefully study this guide and all the regulations identified in Section 1.2 and should then complete the application form, DHEC Form 813. The Department may request additional information when necessary to provide reasonable assurance that the applicant has established an adequate radiation protection program. This regulatory guide identifies the information needed to complete Department Form 813 when applying for a license for a medical use program.

1.1.1 Purpose of Guide

This guide is designed to describe the type and extent of information needed by the Department to evaluate an application for a medical use license and to describe the medical use byproduct material regulations.

1.1.2 Purpose of Appendices to Guide

The regulations require that the licensee develop and implement procedures that will ensure compliance with the regulations. Appendices A through U to this guide describe model radiation safety procedures. Each applicant should carefully read the applicable regulations and model procedures and then decide if the model procedures are appropriate for its specific radiation safety needs. In the application, applicants may certify that they will follow model procedure (appropriate certification language is given at the beginning of each appendix) or may say that they have developed a procedure that is enclosed for review (appropriate reference language is given at the beginning of each appendix).

1.2 APPLICABLE REGULATIONS

In addition to Regulation 61-63, Part IV, other regulations pertaining to the medical use of byproduct material are found in Regulation 61-63, Part VI, "Notices, Instructions, and Reports to Workers; Inspections"; Regulation 61-63, Part III, "Standards for Protection Against Radiation"; Regulation 61-63, Part II, "Licensing of Radioactive Materials", and Regulation 61-63, Part I "General Provisions".

1.3 AS LOW AS REASONABLY ACHIEVABLE (ALARA) PHILOSOPHY

Section RHA 3.4.2, Regulation 61-63 states that the licensee shall use, to the extent practical, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and doses to members of the public that are as low as is reasonably achievable (ALARA). The term “as low as reasonably achievable (ALARA)” means making every reasonable effort to maintain exposures to radiation as far below the dose limits in this part as is practical consistent with the purpose for which the licensed activity is undertaken, taking into account the state of technology, the economics of improvements in relation to state of technology, the economics of improvements in relation to benefits to the public health and safety, and other societal and socioeconomic considerations, and in relation to utilization of nuclear energy and licensed materials in the public interest.

1.3.1 General ALARA Considerations

Each individual who is authorized to use radioactive material should provide appropriate instruction to all individuals who work with or in the vicinity of radioactive material and should ensure that the facility and equipment are adequate for safe use. NUREG-1556, Vol.9, Rev. 1, App. J, ”Model Training Program”, provides the Department's position on training programs for use by medical use licensees. Each worker should follow procedures developed to ensure safety and should promptly report incidents and potential problems to the authorized user or Radiation Safety Officer (RSO).

1.3.2 ALARA in Medical Institutions

Each medical licensee must have a formal ALARA program (see RHA 3.4 of Regulation 61-63. The success of an ALARA program depends on the cooperation of each person who works at the licensee's facility. Management should make a formal policy commitment to the ALARA philosophy and implement that commitment with adequate resources. A Radiation Safety Committee composed of individuals who have special expertise in the safe use of radioactive material is required by RHA 4.13.6 to review uses for safety and ALARA considerations of licensees that are authorized for two or more different types of uses of radioactive material Under Subparts E,F,and H or two or more types of units under Subpart H of Part IV, Regulation 61-63.

The Committee, the RSO, and management should audit the radioactive material program to ensure the continued safe use of radioactive material. In addition to being a member of the Committee, the RSO serves as a technical consultant to the Committee and is also responsible for the day-to-day operation of the radiation safety program. A model ALARA management program is contained in Appendix G to this guide.

1.4 TYPES OF LICENSES

A. The general license provided in Section RHA 2.4.6, Part II of Regulation 61-63, authorizes the registrant to possess and use limited quantities of prepackaged individual doses for *in vivo* uses such as Iodine-131 for blood and plasma volume determinations, Cobalt-58 and Cobalt-60 for intestinal absorption of cyanocobalamin, and chromium-51 for red blood cell volume and survival time determinations. Section RHA 2.4.6 explains the general license requirements and requires the physician to register with the Department and receive a registration number prior to receiving or using the diagnostic radiopharmaceuticals covered by the general license.

B. Section RHA 2.4.3, Part II of Regulation 61-63 establishes a general license authorizing physicians, clinical laboratories, and hospitals to possess certain small quantities of radioactive material (Iodine-125, Iodine-131, Carbon-14, Hydrogen-3, Iron-59, Selenium-75, and mock Iodine-125 reference sources) for *in vitro* clinical or laboratory tests not involving the internal or external administration of radioactive material or the radiation therefrom to human beings or animals. Section RHA 2.4.3 explains the general license requirements and requires the applicant to register with the Department and receive a registration number prior to receiving or using the radioactive material for *in vitro* testing.

C. General Licenses issued to physicians for private practice specify the radioisotopes and the clinical uses that may be performed by the physician to whom the license is issued. Such licenses are issued to physicians who are located in private offices and not on hospital premises. It is not required that a radiation safety committee be formed. The private practice license does not permit other physicians to obtain clinical radioisotope training and experiences under it. Section RHA 4.4.2, Part IV of Regulation 61-63, outlines specific requirements for this type of license. A radiation safety committee is not required for this type of license.

D. Specific licenses of limited scope issued to institutions specify the radioisotopes and the clinical uses that may be performed by physicians named on the institution's license. Institutional licenses provide a means whereby non-approved physicians, under the supervision of physicians named on the license, may obtain basic and clinical radioisotope training and experience that may enable them to qualify as individual users. Training and experience criteria for Radiation Safety Officers, Authorized Medical Physicists, Nuclear Pharmacists, and for experienced members of these categories of use is outlined in Department Regulation 61-63, Part IV, Section***s*** RHA 4.20, 4.21, 4.22, 4.23, and 4.24. Authorized User training for specific modalities of use is outlined in Department Regulation 61-63, Part IV, Sections RHA 4.36, 4.39, 4.43, 4.44, 4.45, 4.54, 4.55, 4.57, and 4.74.

E. Specific licenses of broad scope for medical use, i.e., licenses authorizing multiple quantities and types of radioactive material for unspecified users, are issued to institutions that:

1. have had previous experience operating under a specific license of limited scope, and

2. are engaged in medical research as well as routine diagnosis and therapy using radioisotopes.

Such programs operate under the supervision of a radiation safety committee.

Individual users are not named on the license nor are radioisotopes limited to specified uses. Individual users and procedures are approved by the institution’s radiation safety committee. Physicians may obtain basic and clinical radioisotope training and experience in the use of radiopharmaceuticals in such programs. This type of license is not appropriate for most institutions using radioactive material in medical programs and is fully discussed in a licensing guide dealing specifically with the broad license.

1.5 LICENSE FEES

No application fee is required for most types of licenses. However, the applicant should refer to Section 1.14, "Fees" which concerns annual license fees.

2. FILING AN APPLICATION

A license application for specific licenses for human use should be submitted on Form DHEC-813, "Application for Radioactive Material License" (Exhibit 1). All items on the application form should be completed in sufficient detail for the Department licensing staff to determine that the applicant's equipment, facilities, and radiation protection program are adequate to protect health and minimize danger to life and property.

Since the space provided on Form DHEC-813 is limited, the applicant should submit additional information on separate pages for Items 7-15 listed in the form. Each additional page should contain the item number and the application date at the bottom right hand corner of each page.

The application should be completed in duplicate. The original copy should be mailed to:

S.C. Department of Health and Environmental Control
Bureau of Radiological Health
Division of Radioactive Material
Licensing and Compliance
2600 Bull Street
Columbia, SC 29201

One copy of the application with all attachments should be retained by the applicant, since a license condition will require that the licensee follow the statements and representations set forth in the application and any supplement to it.

3. CONTENTS OF APPLICATION FORM DHEC-813

ITEM 1.a.

Enter the name, mailing address and telephone number of applicant. If the request is for a private license, enter the name of the physician or partnership.

ITEM 1.b.

List the address and locations where radioactive material will be used or stored if other than the address stated in Item 1.a. If multiple addresses are to be used, explain the extent of use at each address and facilities and equipment located at each place of use.

ITEM 2 (Self-explanatory)

ITEM 3

Indicate whether this is an application for a new license, amendment or renewal.

ITEM 4

List the full names of all physicians who will use or directly supervise the use of radioactive material.

ITEM 5

State the name and title of the person designated by, and responsible to, the institution's management for the coordination of the institution's radiation protection program - regularly designated the Radiation Safety Officer (RSO).

ITEM 6 - 6(b) - RADIOACTIVE MATERIAL AND ITEM 7 - PURPOSE

Regulation 61-63, Part IV divides radioactive material for medical use into six types of use. Using the table format of Table 1 as a guide, you may indicate only the types of use you want and the maximum amount. You may say "As needed" in the "Amount" column as shown. For RHA 4.46 implant material, express the total amount in millicuries (mCi). If you plan to have an eye applicator, list it as a separate line item and note its total activity in mCi.

Table 1

Radioactive Material	Amount	Purpose
6a. Material in RHA 4.35	As needed	Medical use
6b. Material in RHA 4.37	As needed	Medical use
6c. Material in RHA 4.40	As needed	Medical use
6d. Implant Material in RHA 4.46	_____mCi	Medical use
6e. Eye applicator in RHA 4.46	_____mCi	Medical use
6f. Material in RHA 4.56	As needed	Medical use
6g. Material in RHA 4.58	_____mCi	Medical use

(Note: Broad scope medical use applicants may request "Any radioactive material with atomic numbers 3 through 83 for medical use.")

If you need other items (for example, more radioactive material for in vitro testing than is allowed under RHA 2.4.3, depleted uranium for linear accelerator shielding, a survey meter calibration source, a teletherapy dosimetry system constancy check source, or material for in vitro, animal, or human studies, or authorization to participate in a protocol approved by a Radioactive Drug Research Committee that has been approved by the Food and Drug Administration), make a separate line entry for each item. (Do not list sources that are authorized in RHA 4.***28***). Number each line entry consecutively following the Part IV material. Each line entry must identify the radionuclide, the physical form, maximum amount on hand expressed in mCi, and the purpose for which the material will be used. If

you do not want all the material listed in Part IV Section, you must identify, line by line, the material that you do want from the section.

ITEMS 8 and 9 - TRAINING AND EXPERIENCE

Responsible individuals are the authorized users, the RSO, the authorized medical physicist, and the authorized nuclear pharmacist. Sections 4.20, 4.21, 4.22, 4.23, 4.24, 4.36, 4.39, 4.43, 4.44, 4.45, 4.54, 4.55, 4.57, and 4.74 of Part IV provide specific criteria for acceptable training and experience for these groups. Note that curriculum vitae do not usually supply all the information needed to evaluate an individual's training and experience.

Authorized users involved in medical use have the following special responsibilities:

1. Examination of patients and medical records to determine if a radiation procedure is appropriate.

2. Prescription of the radiation dosage or dose and how it is to be administered.

3. Actual use of, or direction of technologists or other paramedical personnel in the use of, radioactive material, and

4. Interpretation of results of diagnostic procedures and evaluation of results of therapy procedures.

Numbers 1 through 4 may be delegated to a physician who is under the supervision of an authorized user. Technologists or other personnel may use radioactive material under an authorized user's supervision when permitted under applicable Federal, State, or local laws. Supervision is defined in RHA 4.15.

For in vitro and animal research or other uses that do not involve the intentional exposure of humans, the list of proposed authorized users should include those individuals who will actually be responsible for the safe use of the radioactive material for the requested use. Note which user will be involved with which use by reference to Items 6 and 7 of the application. Those authorized users may direct the use of the radioactive material by technologists or other individuals for the requested use.

8.1 AUTHORIZED USERS FOR MEDICAL USE

1. Make a separate attachment for the RSO and each authorized user. Number the attachments "ATT 8.1.1," ATT 8.1.2" etc. Type the full name of the individual and note, by reference to Items 6a., 6b., etc. which proposed uses are requested for the individual.

2. If a physician has been previously authorized for medical use and only wants to use material permitted by the previous license, you only need to submit the previous license number (if issued by AEC or NRC) or a copy of the license (if issued by an Agreement State) on which the

physician was specifically named as an authorized user.

3. If a physician is certified by a board or an organization recognized by the NRC or an Agreement State (www.nrc.gov), submit Supplement A with Items 1, 2, and 3 completed. A physician certified as a British "Fellow of the Faculty of Radiology" (FFR) or "Fellow of the Royal College of Radiology" (FRCR) should submit a copy of the certificate and evidence of specialization in radiation therapy.

4. Physicians not previously authorized by AEC or NRC or an Agreement State and not certified by an appropriate organization must submit a complete description of their training and experience using Supplements A and B (see Exhibits 2 and 3). This documentation will be reviewed on a case-by-case basis.

5. Broad scope medical use applicants should submit the criteria they will use to evaluate the training and experience of authorized users. Part IV may be used as a guide. The criteria may include a provision that allows that applicant's Radiation Safety Committee to grant case-by-case exceptions.

8.2 AUTHORIZED USERS FOR NONMEDICAL USE

List the full name of each individual proposed as an authorized user for nonmedical use. Submit a complete description of the person's training and experience using Supplement A (Exhibit 2). If the individual was already identified it Item 8.1, no additional attachment is needed here.

8.3 RADIATION SAFETY OFFICER

State the name and title of the person designated by, and responsible to, the applicant's management as RSO. If the RSO is not one of the proposed authorized users, submit a complete description of the individual's training and experience using Supplement A (see Exhibit 2). The RSO should be a full-time employee of the licensee. Even if the licensee employs a consultant to assist the RSO, the licensee is still responsible for the radiation safety program as required by the license.

8.4 TRAINING PROGRAM

Describe your training program for individuals who work with or in the vicinity of radioactive material described in Part IV. See Appendix A of this guide.

8.5 OTHER TRAINING PROGRAMS

Describe your training program for individuals who handle radioactive material other than the Part IV material that you listed in Item 5 of this application. Append it as ATT 8.5.

ITEM 10 - INSTRUMENTATION

Instruments required in a typical nuclear medicine laboratory area:

a) Survey Instruments.

b) Dose calibrators and other instruments to assay radiopharmaceuticals.

c) Diagnostic instruments for all procedures (e.g., gamma camera, well counter, thyroid probe).

d) Other pertinent instrumentation (e.g., liquid scintillation counter, area monitor).

ITEM 11 - METHOD, FREQUENCY, AND STANDARDS USED IN CALIBRATING INSTRUMENTS

1. Submit your procedure for calibrating survey instruments. See Appendix B.

2. Submit your procedure for calibrating the dose calibrator. See Appendix C.

3. Manufacturer's instructions should be followed for calibration and maintenance of diagnostic instrumentation.

ITEM 12 - FILM BADGES AND BIOASSAY PROCEDURES USED

State the name of the organization furnishing film badge or thermoluminescent dosimeter (TLD) service. Specify the frequency with which the badges are changed and evaluated, and give a description of the type, e.g., whole body, or finger badge. See Appendix D of this guide.

Bioassays may be required when individuals work with millicurie quantities of hydrogen-3, iodine-125 or iodine-131 (depending on the chemical and physical form, the procedures followed, and the equipment used). Bioassays may also be required for other radionuclides if the chemical or physical form or procedures and equipment used make it likely that the radioactive material will be ingested, inhaled, or absorbed into the body. Monitoring of occupational intake of radioactive material is required by RHA 3.17.2 for:

Adults likely to receive, in 1 year, an intake in excess of 10 percent of the applicable ALI(s) in Table 1, Columns 1 and 2, of Appendix B, RHA 3.53 and

Minors and declared pregnant women likely to receive, in 1 year, a committed effective dose equivalent in excess of 0.05 rem (0.5 mSv).

The applicant should show in his application that the need for bioassays has been thoroughly considered and that the proposed bioassay program is

appropriate for this intended use of radioactive material.

The following guides may be helpful in establishing bioassay procedures: Department Regulatory Guide "Acceptable Concepts, Models, Equations, and Assumptions for Bioassay Program," "Bioassays for I-125 and I-131" and "Bioassays for H-3". If a commercial bioassay service is to be used, the name and address of the firm should be provided.

ITEM 13 - FACILITIES AND EQUIPMENT

13.1 ANNOTATED DRAWING

Submit an annotated drawing of the room or rooms and adjacent areas where radioactive material will be used. Append it as ATT 13.1. Note the following:

1. The scale. Use the same scale (preferably 1/4 inch = 1 foot) for all drawings.

2. The direction of north.

3. Room numbers and principal use of each room or area (for example, in vitro, hot lab, waiting, examining, imaging, reading, office, file, fresh materials storage, radioactive waste storage, film processor, toilet, closet, hallway).

4. Any shielding available.

5. Additional safety equipment (for example, fume hoods, L-blocks, or fixed area monitors).

See Exhibit 4 for an example.

13.2 IMAGING EQUIPMENT

If you are transporting imaging equipment as part of a mobile nuclear medicine service, describe your procedure for checking the equipment to ensure it has not been damaged in transit. See Appendix E. If you are not going to provide mobile nuclear service, say "NA".

13.3 OTHER EQUIPMENT AND SUPPLIES

Describe other equipment and facilities available for the use and storage of material described in Item 6 of this application other than material described in Part IV. Append it as ATT 13.3.

ITEM 14 - RADIATION SAFETY PROGRAM

14.1 RADIATION SAFETY COMMITTEE/RADIATION SAFETY OFFICER

Describe your Radiation Safety Committee Charter and Radiation Safety Officer delegation of authority. A Radiation Safety Committee must be established by each medical institution licensee that is authorized for two or more different types of radioactive material under Subparts E,F, and H of Regulation 61-63, Part IV or two or more types of units under Subpart H of Regulation 61-63, Part IV. If you are not an institution that falls under these criteria, you only need to submit the Radiation Safety Officer delegation of authority. See Appendix F.

14.2 ALARA PROGRAM

Submit your ALARA program. Each medical licensee must have an ALARA program unless the application is only for devices listed in RHA 4.56 (such institutions will be exempt by license condition). If you are only applying for devices in RHA 4.56, say "NA". Otherwise, see Appendix G.

14.3 LEAK TEST

Submit your procedure for leak-testing sealed sources. See Appendix H.

14.4 SAFE USE OF RADIOPHARMACEUTICALS

Submit a copy of your rules for the safe use of radiopharmaceuticals. See Appendix I.

14.5 SPILL PROCEDURES

Submit a copy of your spill procedures. See Appendix J.

14.6 ORDERING AND RECEIVING

Submit a copy of your procedure for ordering and receiving radioactive material. See Appendix K.

14.7 OPENING PACKAGES

Submit your procedure for opening packages that contain radioactive material. See Appendix L.

14.8 UNIT DOSAGE RECORDS

Submit your procedure for keeping records of unit dosage use. See Appendix M.1.

14.9 MULTIDOSE VIAL RECORDS

Submit your procedure for keeping records of multidose vial use. See Appendix M.2.

14.10 MOLYBDENUM CONCENTRATION RECORDS

Submit your procedure for measuring and recording molybdenum concentration. See Appendix M.3.

14.11 IMPLANT SOURCE USE RECORDS

Submit your procedure for keeping an inventory of implant sources. See Appendix M.4.

14.12 AREA SURVEY PROCEDURES

Submit your area survey procedures. See Appendix N.

14.13 RADIOPHARMACEUTICAL THERAPY

Submit your procedure for radiation safety during radiopharmaceutical therapy. See Appendix P.

14.14 IMPLANT THERAPY

Submit your procedure for radiation safety during implant therapy. See Appendix Q.

14.15 WRITTEN DIRECTIVE PROCEDURES

Submit your procedures for Quality Management Programs. See Appendix R.

14.16 OTHER SAFETY PROCEDURES

Submit safety procedures that will be followed by individuals who handle radioactive material described in Item 6 of this application other than material described in Part IV. Append them as ATT 14.17.

ITEM 15 - WASTE MANAGEMENT

15.1 WASTE DISPOSAL

Submit your procedures for waste disposal. See Appendix R.

15.2 OTHER WASTE DISPOSAL

Submit waste disposal procedures that will be followed for radioactive materials described in Item 6 of this application other than material described in Part IV. Append them as ATT 15.2. (If they are the same as the procedures submitted in Item 15.1, say "See Item 15.1.")

4. PRIVATE PRACTICE LICENSES ONLY

A. Confirm that your private practice has access to a hospital, and adequate facilities are available to hospitalize and monitor radioactive patients whenever it is advisable.

B. If patients treated with therapeutic quantities under this license are admitted to the hospital, you should

1) describe the radiation detection instruments available at the hospital, and

2) submit a copy of radiation safety procedures to be followed.

5. AMENDMENTS TO LICENSES

Licensees are required to conduct their programs in accordance with statements, representations, and procedures contained in the license application and supportive documents. The license must therefore be amended if the licensee plans to make any changes, other than ministerial changes, in the facilities, equipment (including monitoring and survey instruments), procedures, personnel, or radioactive material to be used.

6. RENEWAL OF A LICENSE

An application for renewal of a license should be filed at least 30 days prior to the expiration date. This will ensure that the licensee does not expire until final action on the application has been taken by the Department as provided for in Section 2.12.2, Part II, Department Regulation 61-63.

Renewal applications should be filed on Form DHEC-813, appropriately supplemented, and should contain complete and current information about the applicant's program.

In order to facilitate the review process, the application for renewal should be submitted without references to previous submitted documents and information. If such references cannot be avoided, they should be clear and specific and should identify the pertinent information by date, page and paragraph.

The application should be completed in duplicate. The original should be mailed to:

S.C. Department of Health and Environmental Control
Bureau of Radiological Health
Division of Radioactive Material

Licensing and Compliance
2600 Bull Street
Columbia, South Carolina 29201

One copy of the application, with all attachments, should be retained by the applicant, since the license will require, as a condition, that the institution follow the statements and representations set forth in the application and any supplement to it.

APPENDIX A

Model Training Program
(See RHA 4.7.2)

The following guidance may be used to develop a training program. If you use the frequency and subject listings to develop your training program, you may say on your application, "We will establish and implement the model training program that was published in Appendix A to Medical Programs Licensing Guide Revised March 2008 and have appended a table ATT 8.4 that identifies the groups of workers who will receive training and the method and frequency of training." You may use lectures, videotaped presentations, or demonstrations, for example, as methods of training.

If you prefer, you may develop your own training program for review. If you do so, you should consider for inclusion all the features in the model program. Say on your application, "We have developed a training program for your review that is appended as ATT 8.1." Be sure to include the table that identifies groups of workers, the method of their training, and the frequency of training.

It may not be assumed that safety instruction has been adequately covered by prior occupational training, board certification, etc. Site-specific training should be provided for all workers. Ancillary personnel (e.g., nursing, clerical, housekeeping, security) whose duties may require them to work in the vicinity of radioactive material (whether escorted or not) need to be informed about radiation hazards and appropriate precautions. All training should be tailored to meet the needs of the individuals in attendance. A training program that provides necessary instruction should be written and implemented.

MODEL PROGRAM

Personnel will be instructed:

1. Before assuming duties with, or in the vicinity of, radioactive materials.

2. During annual refresher training.

3. Whenever there is a significant change in duties, regulations, or the terms of the license.

Instruction for individuals in attendance will include the following subjects:

1. Applicable regulations and license conditions.

2. Areas where radioactive material is used or stored.

3. Potential hazards associated with radioactive material in each area where the employees will work.

4. Appropriate radiation safety procedures.

5. Licensee's in-house work rules.

6. Each individual's obligation to report unsafe conditions to the Radiation Safety Officer.

7. Appropriate response to emergencies or unsafe conditions.

8. Worker's right to be informed of occupational radiation exposure and bioassay results.

9. Locations where the licensee has posted or made available notices, copies of pertinent regulations, and copies of pertinent licenses and license conditions (including applications and applicable correspondence).

10. Question and answer period.

APPENDIX B

Model Procedure for Calibrating Survey Instruments
(See RHA 4.26)

You or your contractor may use the following guidance to calibrate survey instruments. If you, or the contractor, follow all the guidance, you may say on your application, "We will establish and implement the model procedure for calibrating survey instruments that was published in Appendix B to Medical Programs Licensing Guide Revised March 2008."

If your procedure does not follow the guidance in the model, you may develop your own procedures for review. If you do so, you should consider for inclusion all the features in the model. Say on your application, "We have developed a survey instrument calibration procedure for your review that is appended as ATT 11.1," and append your survey instrument calibration procedure.

Radiation survey meters should be calibrated with a radioactive source. Electronic calibrations alone are not acceptable. Survey meters must be calibrated at least annually and after servicing. (Battery changes are not considered "servicing".)

MODEL PROCEDURE

1. The source must be approximately a point source.

2. Either the apparent source activity or the exposure rate at a given distance must be traceable by documented measurements to a standard certified within 5 percent accuracy by the National Bureau of Standards.

3. A source that has approximately the same photon energy as the environment in which the calibrated device will be employed should be used for the calibration.

4. The source should be of sufficient strength to give an exposure rate of about 30 mR/hr at 100 cm. Minimum activities of typical sources are 85 millicuries of Cs-137 or 21 millicuries of Co-60.

5. The inverse square law and the radioactive decay law must be used to correct for change in exposure rate due to changes in distance or source decay.

6. A record must be made of each survey meter calibration.

7. A single point on a survey meter scale may be considered satisfactorily calibrated if the indicated exposure rate differs from

the calculated exposure rate by less than 10 percent.

8. Three kinds of scales are frequently used on survey meters:

   a. Meters on which the user selects a linear scale must be calibrated at no less than two points on each scale. The points should be at approximately 1/3 and 2/3 of full scale.

   b. Meters that have a multidecade logarithmic scale must be calibrated at no less than one point on each decade and no less than two points on one of the decades. These points should be at approximately 1/3 and 2/3 of the decade.

   c. Meters that have an automatically ranging digital display device for indicating rates must be calibrated at no less than one point on each decade and at no less than two points on one of the decades. These points should be at approximately 1/3 and 2/3 of the decade.

9. Readings above 1,000 mR/hr need not be calibrated. However, such scales should be checked for operation and approximately correct response.

10. At the time of calibration, the apparent exposure rate from a built-in or owner-supplied check source must be determined and recorded.

11. The report of a survey meter calibration should indicate the procedure used and the data obtained. The description of the calibration will include:

   a. The owner or user of the equipment.

   b. A description of the calibration source, including exposure rate at a specified distance on a specified date, and the calibration procedure;

   c. For each calibration point, the calculated exposure rate, the indicated exposure rate, the deduced correction factor (the calculated exposure rate divided by the indicate exposure rate), and the scale selected on the instrument.

   d. The reading indicated with the instrument in the "battery check" mode (if available on the instrument);

   e. The angle between the radiation flux field and the detector (for external cylindrical GM or ionization-type detectors, this will usually be "parallel" or "perpendicular" indicating photons traveling either parallel with or perpendicular to the central axis of the detector; for instruments with internal detectors, this should be the angle between the flux field and a specified surface of the

instrument);

f. For detectors with removable shielding, an indication of whether the shielding was in place or removed during the calibration procedure;

g. The apparent exposure rate from the check source; and

h. The name of the person who performed the calibration and the date on which the calibration was performed.

The following information will be attached to the instrument as a calibration sticker or tag:

a. The source that was used to calibrate the instrument;

b. The proper deflection in the battery check mode (unless this is clearly indicated on the instrument);

c. For each scale or decade, one of the following is appropriate:

(1) The average correction factor,

(2) A graph or graphs from which the correction factor for each scale or decade may be deduced, or

(3) An indication that the scale was checked for function but not calibrated or an indication that the scale was inoperative.

d. The angle between the radiation flux and the detector during the calibration; and

e. The apparent exposure rate from the check source.

Note: One-word reminders or symbols that are explained on the Survey Meter Calibration Report may be used on the calibration sticker. See Exhibit 5.

APPENDIX C

Model Procedure for Calibrating Dose Calibrator
(See RHA 4.25)

Your or your contractor may use the following model procedure for checking and testing the dose calibrator. If you, or the contractor, follow the model procedure, you may say on your application, "We will establish and implement the model procedure for calibrating our dose calibrator that was published in Appendix C to Medical Programs Licensing Guide Revised March 2008."

If you develop your own dose calibrator calibration procedure for review, you should carefully review all the features in the model procedure. Say on your application, "We have developed a dose calibrator calibration procedure for your review that is appended at ATT 11.2," and append your dose calibrator calibration procedure.

MODEL PROCEDURE

1. Test for the following at the indicated frequency. Consider repair, replacement, or arithmetic correction if the dose calibrator falls outside the suggested tolerances. (These recommended tolerances are more restrictive than those in the regulations to ensure that corrective action will be taken before the dose calibrator is outside permissible tolerances.)

    a. Constancy at least once each day prior to assay of patient dosages (±5 percent).

    b. Linearity at installation and at least quarterly thereafter (±5 percent).

    c. Geometry dependence at installation (±5 percent).

    d. Accuracy at installation and at least annually thereafter (±5 percent).

2. After repair, adjustment, or relocation of the dose calibrator, repeat the above tests as appropriate.

3. Constancy means reproducibility in measuring a constant source over a long period of time. Assay at least one relatively long-lived source such as Cs-137, Co-60, Co-57, or Ra-226 using a reproducible geometry each day before using the calibrator. Consider the use of two or more sources with different photon energies and activities. Use the following procedure:

a. Assay each reference source using the appropriate dose calibrator setting (i.e., use the Cs-137 setting to assay Cs-137).

b. Measure background at the same setting, and subtract or confirm the proper operation of the automatic background subtract circuit if it is used.

c. For each source used, either plot on graph paper or log in a book the background level for each setting checked and the net activity of each constancy source.

d. Using one of the sources, repeat the above procedure for all commonly used radioisotope settings. Plot or log the results.

e. Establish the action level or tolerance for each recorded measurements at which the individual performing the test will automatically notify the chief technician or authorized user of suspected malfunction of the calibrator. These action levels should be written in the log book or posted on the calibrator. The regulation requires repair or replacement if the error exceeds 10 percent.

4. Inspect the instrument on a quarterly basis to ascertain that the measurement chamber liner is in place and that the instrument is zeroed according to the manufacturer's instructions.

5. Linearity means that the calibrator is able to indicate the correct activity over the range of use of that calibrator. This test is done using a vial or syringe of Tc-99m whose activity is at least as large as the maximum activity normally assayed in a prepared radiopharmaceutical kit, in a unit dosage syringe, or in a radiopharmaceutical therapy, whichever is largest.

Decay Method

a. Assay the Tc-99m syringe or vial in the dose calibrator, and subtract background to obtain the net activity in millicuries. Record the date, time to the nearest minute, and net activity on the Dose Calibrator Linearity Test Form. This first assay should be done in the morning at a regular time, for example, 8 a.m.

b. Repeat the assay at about noon, and again at about 4 p.m. Continue on subsequent days until the assayed activity is less than 30 microcuries. For dose calibrators on which you select a range with a switch, select the range you would normally use for the measurement.

c. Convert the time and date information you recorded to hours elapsed since the first assay.

d. On a sheet of semilog graph paper or a copy of the sample form in Exhibit 6, label the logarithmic vertical axis in millicuries and label the linear horizontal axis in hours elapsed. At the top of the graph, note the date and the manufacturer, model number, and serial number of the dose calibrator. Then plot the data.

e. Draw a "best fit" straight line through the data points. For the point farthest from the line, calculate its deviation from the value on the line. (A-observed - A-line)/(A-Line) = deviation.

f. If the worst deviation is more than $\pm$0.05, the dose calibrator should be repaired or adjusted. If this cannot be done, it will be necessary to make a correction table or graph that will allow you to convert from activity indicated by the dose calibrator to "true activity."

g. Put a sticker on the dose calibrator that says when the next linearity test is due.

Shield Method

If you decide to use a set of "sleeves" of various thicknesses to test for linearity, it will first be necessary to calibrate time.

a. Begin the linearity test as described in the decay method described above. After making the first assay, the sleeves can be calibrated as follows. Steps b through d below must be completed within 6 minutes.

b. Put the base and sleeve 1 in the dose calibrator with the vial. Record the sleeve number and indicated activity.

c. Remove sleeve 1 and put in sleeve 2. Record the sleeve number and indicated activity.

d. Continue for all sleeves.

e. Complete the decay method linearity test steps b through g above.

f. From the graph made in step d of the decay method, find the decay time associated with the activity indicated with sleeve 1 in place. This is the "equivalent decay time" for sleeve 1. Record that time with the data recorded in step b.

g. Find the decay time associated with the activity indicated with sleeve 2 in place. This is the "equivalent decay time" for sleeve 2. Record that time with the data recorded in step c.

h. Continue for all sleeves.

i. The table of sleeve numbers and equivalent decay times constitutes the calibration of the sleeve set.

The sleeve set may now be used to test dose calibrators for linearity.

a. Assay the Tc-99m syringe or vial in the dose calibrator, and subtract background to obtain the net activity in millicuries. Record the net activity.

b. Steps c through e below must be completed within 6 minutes.

c. Put the base and sleeve 1 in the dose calibrator with the vial. Record the sleeve number and indicated activity.

d. Remove sleeve 1 and put in sleeve 2. Record the sleeve number and indicated activity.

e. Continue for all sleeves.

f. On a sheet of semilog graph paper or on a copy of the sample form in Exhibit 6, label the logarithmic vertical axis in millicuries, and label the linear horizontal axis in hours elapsed. At the top of the graph, note the date and the model number and serial number of the dose calibrator.

g. Plot the data using the equivalent decay time associated with each sleeve.

h. Draw a "best fit" straight line through the data points. For the point farthest from the line, calculate its deviation from the value on the line.
(A-observed - A-line)/A-line = deviation.

i. If the worst deviation is more than $\pm$0.05, the dose calibrator should be repaired or adjusted. If this cannot be done, it will be necessary to make a correction table or graph that will allow you to convert from activity indicated by the dose calibrator to "true activity."

j. Put a sticker on the dose calibrator that says when the next linearity test is due.

6. Geometry Independence means that the indicated activity does not change with volume or configuration. This test should be done using a syringe that is normally used for injections. Licensees who use generators and radiopharmaceutical kits should also do the test using a vial similar in size, shape, and construction to the radiopharmaceutical kit vials normally used. The following test assumes injections are done with 3-cc plastic syringes and that radiopharmaceutical kits are made in 30-cc glass vials. If you do not use these, change the procedure so that your syringes and vials are tested throughout the range of volumes commonly used.

a. In a small beaker or vial, mix 2 cc of a solution of Tc-99m with an activity concentration between 1 and 10 mCi/ml. Set out a second small beaker or vial with nonradioactive saline. You may also use tap water.

b. Draw 0.5 cc of the Tc-99m solution into the syringe and assay it. Record the volume and millicuries indicated on the Dose Calibrator Geometry and Accuracy Form (See Exhibit 7).

c. Remove the syringe from the calibrator, draw an additional 0.5 cc of nonradioactive saline or tap water, and assay again. Record the volume and millicuries indicated.

d. Repeat the process until you have assayed a 2.0-cc volume.

e. Select as a standard the volume closest to that normally used for injections. For all the other volumes, divide the standard millicuries by the millicuries indicated for each volume. The quotient is a volume correction factor. Alternatively, you may graph the data and draw horizontal 5 percent error lines above and below the chosen "standard volume."

f. If any correction factors are greater than 1.05 or less than 0.95, of if any data points lie outside the 5 percent error lines, it will be necessary to make a correction table or graph that will allow you to convert from "indicated activity" to "true activity." If this is necessary, be sure to label the table or graph "syringe geometry dependence," and note the date of the test and the model number and serial number of the calibrator.

g. To test the geometry dependence for a 30-cc glass vial, draw 1.0 cc of the Tc-99m solution into a syringe and then inject it into the vial. Assay the vial. Record the volume and millicuries indicated.

h. Remove the vial from the calibrator and, using a clean syringe, inject 2.0 cc of nonradioactive saline or tap water, and assay again. Record the volume and millicuries indicated.

i. Repeat the process until you have assayed a 19.0-cc volume. The entire process must be completed within 10 minutes.

j. Select as a standard the volume closest to that normally used for mixing radiopharmaceutical kits. For all the other volumes, divide the standard millicuries by the millicuries indicated for each volume. The quotient is a volume correction factor. Alternatively, you may graph the data and draw horizontal 5 percent error lines above and below the chosen "standard volume."

k. If any correction factors are greater than 1.05 or less than 0.95 or if any data points lie outside the 5 percent error lines, it will be necessary to make a correction table or graph that will allow you to convert from "indicated activity" to "true activity." If this is necessary, be sure to label the table or graph "vial geometry dependence," and note the date of the test and the model number and serial number of the calibrator.

7. Accuracy means that, for a given calibrated reference source, the indicated millicurie value is equal to the millicurie value determined by the National Bureau of Standards (NBS) or by the supplier who has compared that source to a source that was calibrated by the NBS. Certified sources are available from the NBS and from many radioisotope suppliers. At least two sources with different principal photon energies (such as Co-57, Co-60, or Cs-137) should be used. The regulations require that one must have a principal photon energy between 100 keV and 500 keV. The regulations also require that, if a Ra-226 source is used, it must be at least 10 microcuries; other sources must be at least 50 microcuries. Consider using at least one reference source whose activity is within the range of activities normally assayed.

   a. Assay a calibrated reference source at the appropriate setting (i.e., use the Co-57 setting to assay Co-57), and then remove the source and measure background. Subtract background from the indicated activity to obtain the net activity. Record this measurement on the Dose Calibrator Geometry and Accuracy Form. Repeat for a total of three determinations.

   b. Average the three determinations. The average value should be within 5 percent of the certified activity of the reference source, mathematically corrected for decay.

   c. Repeat the procedure for other calibrated reference sources.

   d. If the average value does not agree, within 5 percent, with the certified value of the reference source, the dose calibrator may need to be repaired or adjusted. The regulation requires repair or replacement if the error exceeds 10 percent.

   e. At the same time the accuracy test is done, assay the source that will be used for the daily constancy test (it need not be a certified reference source) on all commonly used radioisotope settings. Record the settings and indicated millicurie values with the accuracy data.

   f. Put a sticker on the dose calibrator that says when the next accuracy test is due.

8. The RSO will review and sign the records of all geometry, linearity, and accuracy tests. See Exhibits 6 and 7.

APPENDIX D

Model Personnel External Exposure Monitoring Program

You may use the following model program to monitor personnel external exposure. If you follow the guidance in the program, you may say on your application, "We will establish and implement the model personnel external exposure monitoring program published in Appendix D to Medical Programs Licensing Guide Revised March 2008."

If you prefer, you may develop your own program for review. If you do, you should consider for inclusion all the features in the model program. Say on your application, "We have developed an external exposure monitoring program for your review that is appended as ATT 12," and append your monitoring program.

MODEL PROGRAM

1. The RSO will promptly review all exposure reports to look for workers or groups of workers whose exposure is unexpectedly high or low. This procedure does not apply to backup monitor records, for example, pocket ionization chambers, when the monitor of record is a film or thermoluminescence dosimeter (TLD).

2. All individuals who are occupationally exposed to ionizing photon radiation on a regular basis will be issued a film or TLD whole body monitor that will be processed by a contract service on a monthly basis.

3. All individuals who, on a regular basis, handle radioactive material that emits ionizing photons will be issued a film or TLD finger monitor that will be processed by a contract service on a monthly basis.

4. All individuals who are occupationally exposed to radiation on a regular basis will be issued a film or whole body TLD monitor that will be processed by a contract service on a monthly basis.

5. Other individuals who are exposed to radiation on an occasional basis such as security personnel who deliver packages, secretarial personnel who work in the nuclear medicine clinic but do not work with patients, and nurses who occasionally care for patients who have received diagnostic dosages will not normally be issued exposure monitors.

APPENDIX E

Model Procedure for Checking Equipment Used in Mobile Nuclear Medicine Service (See RHA 4.33 and RHA 4.99)

The Department normally limits its review of equipment quality assurance programs to those programs developed for radiation safety equipment. However, when delicate imaging equipment is transported from one location of use to another, e.g., by a mobile nuclear medicine service, it is reasonable to assume that it may suffer damage in transit. Therefore, the Department requires that mobile nuclear medicine services have an imaging equipment quality assurance program to ensure that the use of radioactive material will not be inimical to the public health and safety. Mobile nuclear medicine services should also check ventilation equipment if gases or aerosols will be used.

You may use the following procedure to ensure the proper operation of imaging equipment that has been transported. If you follow the procedure, you may say on your application, "We will establish and implement the model procedure for ensuring equipment performance that was published in Appendix E to Medical Programs Licensing Guide Revised March 2008."

If you want to develop your own procedure for review, you should consider for inclusion all the features in the model procedure and the procedure recommended by the manufacturer. Say on your application, "We have developed a procedure for ensuring equipment performance for your review that is appended as ATT 13.2," and append your imaging equipment quality assurance procedure.

MODEL PROCEDURE

Survey Meter

Check the survey meter with the dedicated check source at each location of use. Material may not be used if the survey meter is not working. There is no need to keep a record of these checks.

Camera

1. Perform the following checks daily at each location of use before administering radioactive material:

    a. Peak each camera according to the manufacturer's instructions.

b. Using either Tc-99m or Co-57, perform an extrinsic flood field with a frequently used collimator in place, or perform an intrinsic flood field test. Accumulate at least 1,000,000 counts for small-field-of-view cameras and 3,000,000 counts for large-field-of-view cameras. Process the image as if it were an image of a patient.

c. Do not administer material until an authorized user or a designated technologist approves the camera for use.

d. You do not have to make a permanent record of these daily checks.

2. Perform the following checks weekly:

a. With the same frequency used collimator in place, image a flood source and either a parallel-line-equal-space (PLES), bar, orthogonal-hole (OH) or resolution-quadrant phantom with the flood field as a source.

b. If a PLES or bar phantom is used, rotate it 90^{o} so that the camera is tested for both vertical and horizontal geometric linearity.

c. If a resolution-quadrant phantom is used, rotate it so that each quadrant is imaged in each quadrant of the crystal. Then turn it over and again image it four more times. This procedure will check both resolution and horizontal and vertical geometric linearity in each quadrant of the crystal.

d. Process the images as if they were images of a patient. Mark them clearly to indicate image orientation, source activity, and date.

e. Retain the images for 2 years.

3. Perform the following safety checks after repairs and quarterly:

a. Check the motion interlocks by activating the emergency-off switches on the camera. With the camera in motion, activation of the emergency-off switch should stop the motion. If this might jeopardize imaging components in the system, perform only the checks described in paragraph 3.b.

b. Check the motion switches. Put the camera in motion and first release just the direction switch to stop the motion. Then put the camera back in motion and release just the dead-man switch. Test all motion switches and all directions in this manner. Release of either the motion switch or the dead-man switch alone

should disable the camera motion. If this is not the case, repair the camera before clinical use.

4. Set the equipment in the same manner each time checks are run. Make a record of all these checks. Keep a separate file or ring binder for each camera. Retain the record for 2 years.

Ventilation

If gases or aerosols will be used, check the ventilation supply, exhaust vents, and collection devices for operation with tissue paper or a velometer. There is no need to keep a record of these checks.

APPENDIX F

Model Radiation Safety Committee Charter and Radiation Safety Officer Delegation of Authority (See RHA 4.13)

You may use the following text as it appears here, saying on your application, "We will issue the model Radiation Safety Committee Charter and Radiation Safety Officer Delegation of Authority that was published in Appendix F to Medical Programs Licensing Guide Revised February 2007."

If you prefer, you may develop your own statement of authority, duties, administrative procedures, and delegation of authority. If you do so, you should consider for inclusion all the features in the model text. Say on your application, "We will issue the Radiation Safety Committee Charter and Radiation Safety Officer Delegation of Authority that are appended as ATT 14.1," and append your charter and delegation.

MODEL CHARTER

Charge. The Committee shall:

1. Ensure that licensed material will be used safely. This includes review as necessary of training programs, equipment, facility, supplies, and procedures;

2. Ensure that licensed material is used in compliance with Department regulations and the institutional license;

3. Ensure that the use of licensed material is consistent with the ALARA philosophy and program;

4. Establish a table of investigational levels for individual occupational radiation exposures; and

5. Identify program problems and solutions.

Responsibilities. The Committee shall:

1. Be familiar with all pertinent Department regulations, the license application, the license, and amendments;

2. Review the training and experience of the proposed authorized users, the Radiation Safety Officer (RSO), and the medical physicists to determine that their qualifications are sufficient to enable the individuals to perform their duties safely and are in accordance with the regulations and the license;

3. Review on the basis of safety and approve or deny, consistent with the limitations of the regulations, the license, and the ALARA philosophy, all requests for authorization to use radioactive material within the institution;

4. Prescribe special conditions that will be required during a proposed method of use of radioactive material such as requirements for bioassays, physical examinations of users, and special monitoring procedures;

5. Review quarterly the RSO's summary report of the occupational radiation exposure records of all personnel, giving attention to individuals or groups of workers whose occupational exposure appears excessive;

6. Establish a program to ensure that all persons whose duties may require them to work in or frequent areas where radioactive materials are used (e.g., nursing, security, housekeeping, physical plant) are appropriately instructed as required by RHA 6.3, Department Regulation 61-63;

7. Review at least annually the RSO's summary report of the entire radiation safety program to determine that all activities are being conducted safely, in accordance with Department regulations and the conditions of the license, and consistent with the ALARA program and philosophy. The review must include an examination of records, reports from the RSO, results of Department inspections, written safety procedures, and the adequacy of the management control system;

8. Recommend remedial action to correct any deficiencies identified in the radiation safety program;

9. Maintain written minutes of all Committee meetings, including members in attendance and members absent, discussions, actions, recommendations, decisions, and numerical results of all votes taken; and

10. Ensure that the radioactive material license is amended if required prior to any changes in facilities, equipment, policies, procedures, and personnel.

Administrative Information

1. The Committee shall meet as often as necessary to conduct its business but not less than once in each calendar quarter.

2. Membership must include one authorized user for each type of use authorized by the license, the RSO, a representative of the nursing service, and a representative of management who is neither an authorized user nor an RSO. Management may appoint alternate members to participate in meetings in the case of absence of principal members and should consider appointing as adjunct members representatives from security, physical plant, housekeeping, and other departments. (Adjunct members should abstain from balloting on radiation safety technical questions such as Items 2 through 5 in the "Responsibilities" section above.)

3. To establish a quorum, one-half of the Committee's membership, including the RSO and the management representative, must be present.

4. To the extent that they do not interfere with the mission of the Committee, management may assign other responsibilities such as x-ray radiation safety, quality assurance oversight, and research project review and approval.

MODEL DELEGATION OF AUTHORITY

Memo To: All Employees
From: Chief Executive Officer
Subject: Delegation of Authority

_____ has been appointed Radiation Safety Officer and is responsible for ensuring the safe use of radiation. The Radiation Safety Officer is responsible for managing the radiation safety program; identifying radiation problems; initiating, recommending, or providing corrective actions; verifying implementation of corrective actions; and ensuring compliance with regulations. The Radiation Safety Officer is hereby delegated the authority necessary to meet those responsibilities.

The Radiation Safety Officer is also responsible for assisting the Radiation Safety Committee in the performance of its duties and serving as its secretary.

APPENDIX G

Model Program for Maintaining Occupational Radiation Exposure
at Medical Institutions ALARA
(See Part IV, Subpart B and Part III, RHA 3.4)

You may use the text as it appears here, saying on your application, "We will establish and implement the model ALARA program that was published in Appendix G to Medical Programs Licensing Guide Revised March 2008."

If you prefer, you may develop your own ALARA program for Department review. If you do so, you should consider for inclusion all the features in the model. Carefully review the requirements of RHA 4.***13***. Say on your application, "We have developed an ALARA program for your review that is appended as ATT 14.2," and append your program.

ALARA PROGRAM

_____
Licensee's Name

_____
Date

1. Management Commitment

   a. We, the management of this (medical facility, hospital, etc.) are committed to the program described herein for keeping individual and collective doses as low as is reasonably achievable (ALARA). In accord with this commitment, we hereby describe an administrative organization for radiation safety and will develop the necessary written policy, procedures, and institutions to foster the ALARA concept within our institution. The organization will include a Radiation Safety Committee (RSC) and a Radiation Safety Officer (RSO).

   b. We will perform a formal annual review of the radiation safety program, including ALARA considerations. This will include reviews of operating procedures and past dose records, inspections, etc., and consultations with the radiation safety staff or outside consultants.

   c. Modifications to operating and maintenance procedures and to equipment and facilities will be made if they will reduce exposures unless the cost, in our judgment, is considered to be unjustified. We will be able to demonstrate, if necessary, that

improvements have been sought, that modifications have been considered, and that they have been implemented when reasonable. If modifications have been recommended but not implemented, we will be prepared to describe the reasons for not implementing them.

d. In addition to maintaining doses to individuals as far below the limits as is reasonably achievable, the sum of the doses received by all exposed individuals will also be maintained at the lowest practicable level. It would not be desirable, for example, to hold the highest doses to individuals to some fraction of the applicable limit if this involved exposing additional people and significantly increasing the sum of radiation doses received by all involved individuals.

2. Radiation Safety Committee

a. Review of Proposed Users and Uses

(1) The RSC will thoroughly review the qualifications of each applicant with respect to the types and quantities of materials and methods of use for which application has been made to ensure that the applicant will be able to take appropriate measures to maintain exposure ALARA.

(2) When considering a new use of byproduct material, the RSC will review the efforts of the applicant to maintain exposure ALARA.

(3) The RSC will ensure that the users justify their procedures and that individual and collective doses will be ALARA.

b. Delegation of Authority

(The judicious delegation of RSC authority is essential to the enforcement of an ALARA program.)

(1) The RSC will delegate authority to the RSO for enforcement of the ALARA concept.

(2) The RSC will support the RSO when it is necessary for the RSO to assert authority. If the RSC has overruled the RSO, it will record the basis for its action in the minutes of the quarterly meeting.

c. Review of ALARA Program

(1) The RSC will encourage all users to review current procedures and develop new procedures as appropriate to implement the ALARA concept.

(2) The RSC will perform a quarterly review of occupational radiation exposure with particular attention to instances in which the

investigational levels in Table 1 are exceeded. The principal purpose of this review is to assess trends in occupational exposure as an index of the ALARA program quality and to decide if action is warranted when investigational levels are exceeded (See Section 6 below for a discussion of investigational levels).*

Table 1

Investigational Levels

	Investigational Levels (mrems per calendar quarter)	
	Level I	Level II
1. Whole body; head and trunk; active blood-forming organs; lens of eyes; or gonads	125	375
2. Hands and forearms; feet and ankles	1875	5625
3. Skin of whole body*		

*Not normally applicable to medical use operations except those using significant quantities of beta-emitting isotopes.

(3) The RSC will evaluate our institution's overall efforts for maintaining doses ALARA on an annual basis. This review will include the efforts of the RSO, authorized users, and workers as well as those of management.

*The Department investigational levels in this program are not new dose limits but, as noted in ICRP Report 26, "Recommendations of the International Commission on Radiological Protection," serve as check points above which the results are considered sufficiently important to justify investigations.

3. Radiation Safety Officer

a. Annual and Quarterly Review

(1) Annual review of the radiation safety program. The RSO will perform an annual review of the radiation safety program for adherence to ALARA concepts. Reviews of specific methods of use may be conducted on a more frequent basis.

(2) Quarterly review of occupational exposures. The RSO will review at least quarterly the external radiation doses of authorized users and workers to determine that their doses are ALARA in accordance with the provisions of Section 6 of this program and will prepare a summary report for the RSC.

(3) Quarterly review of records of radiation surveys. The RSO will review radiation surveys in unrestricted and restricted areas to determine that dose rates and amounts of contamination were at ALARA levels during the previous quarter and will prepare a summary report for the RSC.

b. Education Responsibilities for ALARA Program

(1) The RSO will schedule briefings and educational sessions to inform workers of ALARA program efforts.

(2) The RSO will ensure that authorized users, workers, and ancillary personnel who may be exposed to radiation will be instructed in the ALARA philosophy and informed that management, the RSC, and the RSO are committed to implementing the ALARA concept.

c. Cooperative Efforts for Development of ALARA Procedures

Radiation workers will be given opportunities to participate in formulating the procedures that they will be required to follow.

(1) The RSO will be in close contact with all users and workers in order to develop ALARA procedures for working with radioactive materials.

(2) The RSO will establish procedures for receiving and evaluating the suggestions of individual workers for improving health physics practices and will encourage the use of those procedures.

d. Reviewing Instances of Deviation from Good ALARA Practices

The RSO will investigate all known instances of deviation from good ALARA practices and, if possible, will determine the causes. When the cause is known, the RSO will implement changes in the program to maintain doses ALARA.

4. Authorized Users

a. New Methods of Use Involving Potential Radiation Doses

(1) The authorized user will consult with the RSO and/or RSC during the planning stage before using radioactive materials for new uses.

(2) The authorized user will review each planned use of

radioactive materials to ensure that doses will be kept ALARA. Trial runs may be helpful.

b. Authorized User's Responsibility to Supervised Individuals

(1) The authorized user will explain the ALARA concept and the need to maintain exposures ALARA to all supervised individuals.

(2) The authorized user will ensure that supervised individuals who are subject to occupational radiation exposure are trained and educated in good health physics practices and in maintaining exposures ALARA.

5. Individuals Who Receive Occupational Radiation Doses

a. Workers will be instructed in the ALARA concept and its relationship to work procedures and work conditions.

b. Workers will be instructed in recourses available if they feel that ALARA is not being promoted on the job.

6. Establishment of Investigational Levels in Order to Monitor Individual Occupational External Radiation Doses.

This institution hereby establishes investigational levels for occupational external radiation doses which, when exceeded, will initiate review or investigation by the RSC and/or the RSO. The investigational levels that we have adopted are listed in Table 1. These levels apply to the exposure of individual workers.

The RSO will review and record on S.C. Form 5 "Occupational Exposure Record for a Monitoring Period," or an equivalent form (e.g., dosimeter processor's report) results of personnel monitoring on an annual basis as required by RHA 3.39.

a. Personnel dose less than Investigational Level I.

Except when deemed appropriate by the RSO, no further action will be taken in those cases where an individual's dose is less than Table 1 values for the Investigational Level I.

b. Personnel dose equal to or greater than Investigation Level I but less than Investigational Level II.

The RSO will review the dose of each individual whose quarterly dose equals or exceeds Investigational Level I and will report the results of the reviews at the first RSC meeting following the quarter when the dose was recorded. If the dose does not equal or exceed Investigational Level II, no action related

specifically to the exposure is required unless deemed appropriate by the Committee. The Committee will, however, review each such dose in comparison with those of others performing similar tasks as an index of ALARA program quality and will record the review in the Committee minutes.

c. Personnel dose equal to or greater than Investigational Level II.

The RSO will investigate in a timely manner the causes of all personnel doses equaling or exceeding Investigational Level II and, if warranted, will take action. A report of the investigation, any actions taken, and a copy of the individual's S.C. Form 5 or its equivalent will be presented to the RSC at its first meeting following completion of the investigation. The details of these reports will be included in the RSC minutes.

d. Reestablishment of investigational levels to levels above those listed in Table 1.

In cases where a worker's or a group of workers' doses need to exceed an investigational level, a new, higher investigational level may be established for that individual or group on the basis that it is consistent with good ALARA practices. Justification for new investigational levels will be documented.

The RSC will review the justification for and must approve or disapprove all revisions of investigational levels.

7. Signature of Certifying Official*

I hereby certify that this institution has implemented the ALARA Program set forth above.

_____
Signature

_____
Name (print or type)

_____
Title

*The person who is authorized to make commitments for the administration of the institution (e.g., hospital administrator).

APPENDIX H

Model Procedure for Leak-Testing Sealed Sources
(See RHA 4.29)

You or your contractor may use the following model procedure to leak-test sealed sources. If you, or the contractor, follow the model procedure you may say on your application, "We will establish and implement the model procedure for leak-testing sealed sources that was published in Appendix H to Medical Licensing Guide Revised March 2008."

You may develop your own procedure for review. If you do so, you should consider for inclusion all the features in the model and carefully review the requirements of RHA 4.29. Say on your application, "We have developed a leak-test procedure for your review that is appended as ATT 14.3," and append your leak-test procedure.

MODEL PROCEDURE

1. Make a list of all sources to be tested. This should include at least the isotope, the activity on a specified date, and the physical form.

2. If you will be testing sources stronger than a few millicuries, set out a survey meter, preferably with a speaker, so you can monitor your exposure rate.

3. Prepare a separate wipe sample for each source. A cotton swab, injection prep pad, filter paper, or tissue paper is suitable. Number each wipe so you will know for which source it is to be used. Samples should be taken as follows:

    a. For small sealed sources, it may be easier to wipe the entire accessible surface area. Pay particular attention to seams and joints. However, do not wipe the port of beta applicators.

    b. For larger sealed sources and devices (survey meter calibrator, bone mineral analyzer source), take the wipe near the radiation port and on the activating mechanism.

    c. For teletherapy machines, take the wipe with the source in the off position. Wipe the area near the shutter mechanism, taking care to touch neither field light and mirror nor crosshairs. Also wipe the primary and secondary collimators and trimmers.

    d. If you are testing radium sources at the same time you are testing Department-licensed sources, they should also be checked

for radon leakage. This can be done by submerging the source in a vial of fine-grained charcoal or cotton for a day. Then remove the source and analyze the adsorbent sample as described below. A survey should be done to be sure the sources are adequately shielded during the leak-test period.

4. The samples will be analyzed as follows:

   a. Select an instrument that is sufficiently sensitive to detect 0.005 microcuries. For beta sources, a proportional flow counter, liquid scintillation counter, or thin-end-window GM survey meter may be appropriate. For gamma sources, a crystal with a ratemeter or scaler or a GM survey meter may be appropriate. Dose calibrators used in nuclear medicine are not sufficiently sensitive.

   b. To estimate the detection efficiency of the analyzer used to assay the wipe samples, assay a check source that has the same isotope as the sealed source and whose activity is certified by the supplier. If one is not available, it will be necessary to use a certified check source with a different isotope that has a similar spectrum. If calculations demonstrate that the instrument is not sufficiently sensitive to detect 0.005 microcuries, a different instrument must be used.

   c. Assay the wipe sample. It must be in the same geometry relative to the detector as was the certified check source.

   d. Record the wipe sample counts per minute. Then calculate and record the estimated activity in microcuries on the wipe sample.

   e. Continue the same analysis procedure for all wipe samples.

   f. If the wipe sample activity is 0.005 microcuries or greater, notify the RSO. The source must be withdrawn from use to be repaired or discarded. If it is a source distributed under an NRC or Agreement State license, the Department must be notified.

   g. Sign and date the list of sources, data, and calculations.

APPENDIX I

Model Rules for Safe Use of Radiopharmaceuticals
(See RHA 4.13)

You may use the following model rules as they appear here, saying on your application, "We will establish and implement the model safety rules published in Appendix I to Medical Programs Licensing Guide Revised March 2008."

If you prefer, you may develop your own rules for safe use of radiopharmaceuticals for review. If you do so, you should consider for inclusion all the items in the model rules and carefully review the requirements of Part IV. Say on your application, "We have developed rules for the safe use of radiopharmaceuticals for your review that are appended as ATT 14.4," and append your model rules for the safe use of radiopharmaceuticals.

MODEL RULES

1. Wear laboratory coats or other protective clothing at all times in areas where radioactive materials are used.

2. Wear disposable gloves at all times while handling radioactive materials.

3. Either after each procedure or before leaving the areas, monitor your hands for contamination in a low-background area with a crystal probe or camera.

4. Use syringe shields for routine preparation of multi-dose vials and administration of radiopharmaceuticals to patients, except in those circumstances in which their use is contraindicated (e.g., recessed veins, infants). In these exceptional cases, consider the use of other protective methods such as remote delivery of the dose (e.g., through use of a butterfly valve).

5. Do not eat, drink, smoke, or apply cosmetics in any area where radioactive material is stored or used.

6. Do not store food, drink, or personal effects in areas where radioactive material is stored or used.

7. Wear personnel monitoring devices at all times while in areas where radioactive materials are used or stored. These devices should be worn as prescribed by the Radiation Safety Officer. When not being

worn to monitor occupational exposures, personnel monitoring devices should be stored in the work place in a designated low-background area.

8. Wear a finger exposure monitor during the elution of generators; during the preparation, assay, and injection of radiopharmaceuticals; and when holding patients during procedures.

9. Dispose of radioactive waste only in designated, labeled, and properly shielded receptacles.

10. Never pipette by mouth.

11. Wipe-test radioactive material storage, preparation, and administration areas weekly for contamination. If necessary, decontaminate or secure the area for decay.

12. With a radiation detection survey meter, survey the generator storage, kit preparation, and injection areas daily for contamination. If necessary, decontaminate or secure the area for decay as appropriate.

13. Confine radioactive solutions in shielded containers that are clearly labeled. Radiopharmaceutical multidose diagnostic vials and therapy vials should be labeled with the isotope, the name of the compound, and the date and time of receipt or preparation. A log book should be used to record the preceding information and total prepared activity, specific activity as mCi/cc at a specified time, total volume prepared, total volume remaining, the measured activity of each patient dosage, and any other appropriate information. Syringes and unit dosages should be labeled with the radiopharmaceutical name or abbreviation, type of study, or the patient's name.

14. Assay each patient dosage in the dose calibrator before administering it. Do not use a dosage if it is more than 10 percent off from the prescribed dosage, except for prescribed dosages of less than 10 microcuries. When measuring the dosage, you need not consider the radioactivity that adheres to the syringe wall or remains in the needle. Check the patient's name and identification number and the prescribed radionuclide, chemical form, and dosage before administering.

15. Always keep flood sources, syringes, waste, and other radioactive material in shielded containers.

16. Because even sources with small amounts of radioactivity exhibit a high dose rate on contact, you should use a cart or wheelchair to move flood sources, waste, and other radioactive material.

APPENDIX J

Model Emergency Procedures
(See RHA 4.13 and 3.4)

You may use the following model spill procedures as they appear here, saying on your application, "We will establish and implement the model spill procedures published and Appendix J to Medical Programs Licensing Guide Revised March 2008."

If you prefer, you may develop your own spill procedures for review. If you do so, you should consider for inclusion all the items in the model procedures. Say on your application, "We have developed spill procedures for your review that are appended as ATT 14.5," and append your spill procedures.

MODEL PROCEDURES

Minor Spills of Liquids and Solids

1. Notify persons in the area that a spill has occurred.

2. Prevent the spread of contamination by covering the spill with absorbent paper.

3. Clean up the spill using disposable gloves and absorbent paper. Carefully fold the absorbent paper with the clean side out and place in a plastic bag for transfer to a radioactive waste container. Also put contaminated gloves and any other contaminated disposable material in the bag.

4. Survey the area with a low-range radiation detector survey meter. Check the area around the spill. Also check your hands, clothing, and shoes for contamination.

5. Report the incident to the Radiation Safety Officer (RSO).

6. The RSO will follow up on the cleanup of the spill and will complete a radioactive spill report and a radioactive spill contamination survey.

Major Spills of Liquids and Solids

1. Clear the area. Notify all persons not involved in the spill to vacate the room.

2. Prevent the spread of contamination by covering the spill with

absorbent paper, but do not attempt to clean it up. To prevent the spread of contamination, limit the movement of all personnel who may be contaminated.

3. Shield the source if possible. This should be done only if it can be done without further contamination or a significant increase in radiation exposure.

4. Close the room and lock or otherwise secure the area to prevent entry.

5. Notify the RSO immediately.

6. Decontaminate personnel by removing contaminated clothing and flushing contaminated skin with lukewarm water and then washing with mild soap. If contamination remains, induce perspiration by covering the area with plastic. Then wash the affected area again to remove any contamination that was released by the perspiration.

7. The RSO will supervise the cleanup of the spill and will complete a radioactive spill report and a radioactive spill contamination survey.

The following is <u>not</u> part of the model spill procedure:

<u>Major Spills and Minor Spills</u>

The decision to implement a major spill procedure instead of a minor spill procedure depends on many incident-specific variables such as the number of individuals affected, other hazards present, likelihood of spread of contamination, and types of surfaces contaminated as well as the radiotoxicity of the spilled material. For some spills of short-lived radionuclides the best spill procedure may be restricted access pending complete decay.

Table J-1, which may be used as general guidance to determine whether a major spill procedure or a minor spill procedure should be implemented, was developed based on a comparison of information from the following sources:

Reference: NCRP Report No. 111, “Developing Radiation Emergency Plans for Academic, Medical, and Industrial Facilities,” 1991, contains helpful information. It is available from the National Council on Radiation Protection and Measurements, 7910 Woodmont Avenue, Suite 400, Bethesda, Maryland 20814-3095. NCRP’s telephone numbers are: (301) 657-2652 or 1-800-229-2652.

Table J-1 may need to be modified before being used for guidance in a specific area of use.

TABLE J-1

Relative Hazards of Common Radionuclides

Estimate the amount of radioactivity spilled. Initiate a major or minor spill procedure based on the following dividing line. Spills above these millicurie amounts are considered major, below are considered minor.

Radionuclide	Millicuries	Radionuclide	Millicuries
P-32	>1	Tc-99m	100
Cr-51	100	In-111	10
Co-57	10	I-123	10
Co-58	10	I-125	1
Fe-59	1	I-131	1
Co-60	1	Sm-153	10
Ga-67	10	Yb-169	10
Se-75	1	Hg-197	100
Sr-85	10	Au-198	10
Sr-89	1	Tl-201	100

Spill Kit

You may also want to consider assembling a spill kit that contains:

6 pairs disposable gloves, 1 pair housekeeping gloves
2 disposable lab coats
2 paper hats
2 pairs shoe covers
1 roll absorbent paper with plastic backing
6 plastic trash bags with twist ties
"Radioactive Material" labeling tape
1 china pencil or marking pen
3 prestrung "Radioactive Material" labeling tags
Supplies for 10 contamination wipe samples
Instructions for "Emergency Procedures"
Clipboard with one copy of Radioactive Spill Report Form
Pencil
Masking Tape

Emergency Surgery of Patients Who Have Received Therapeutic Amounts of Radionuclides

1. If emergency surgery is performed within the first 24 hours following the administration of I-131 sodium iodide, fluids (e.g., blood, urine) will be carefully removed and contained in a closed system.

2. Protective eyewear will be worn by the surgeon and any personnel involved in the surgical procedure for protection of the eyes from possible splashing of radioactive material and exposure from beta radiation (if applicable).

3. The Radiation Staff will direct personnel in methods to keep doses ALARA during surgical procedures.

4. If any injury occurs during surgery that results in a cut or tear in the glove used, the individual involved will be monitored to determine if radioactive material was introduced into the wound. The RSO will be informed of any possible radiation hazard.

Autopsy of Patients Who Have Received Therapeutic Amounts of Radionuclides.

1. Immediately notify the authorized user in charge of the patient and the RSO upon the death of a therapy patient.

2. An autopsy will be performed only after consultation and permission from the RSO. Radiation safety staff should evaluate the radiation hazard(s), direct personnel in safety and protection, and suggest suitable procedures in order to keep doses ALARA during the autopsy.

3. Protective eyewear should be worn by the pathologist and assisting staff for protection from possible splashing of radioactive material. Consider the need for protection against exposure from high energy beta rays in cases involving therapy with P-32 and Y-90.

4. Remove tissues containing large activities early to help reduce exposure of autopsy personnel. Shield and dispose of contaminated tissues in accord with license conditions. In some cases, exposure reduction may be accomplished by removing tissues for dissection to a location where the exposure rate is lower.

5. If an injury occurs during the autopsy that results in a cut or tear in the glove, monitor the wound and decontaminate as appropriate to the situation; inform radiation safety staff.

APPENDIX K

Model Guidance for Ordering and Receiving Radioactive Material

You may use the following guidance to control the ordering and receipt of radioactive material. If you follow all the guidance, you may say on your application, "We will establish and implement the model guidance for ordering and receiving radioactive material that was published in Appendix K to Medical Programs Licensing Guide Revised March 2008."

If your procedure does not follow all the guidance in the model, you may develop your own procedure for review. If you do so, you should consider for inclusion all the features in the model and carefully review the requirements. Say on your application, "We have developed a procedure for ordering and receiving radioactive material for your review that is appended as ATT 14.6," and append your procedure for ordering and receiving radioactive material.

MODEL GUIDANCE

1. The Radiation Safety Officer (RSO) or a designee must authorize each order for radioactive materials and ensure that the requested materials and quantities are authorized by the license for use by the requesting authorized user and that possession limits are not exceeded.

2. The RSO will establish and maintain a system for ordering and receiving radioactive material. The system must contain the following information:

   a. For routinely used materials

      (1) Written records that identify the authorized user or department, isotope, chemical form, activity, and supplier will be made.

      (2) The above records will be checked to confirm that material received was ordered through proper channels.

   b. For occasionally used materials (e.g., therapeutic dosages)

      (1) The authorized user who will perform the procedure will make a written request that indicates the isotope, radiopharmaceutical, activity, and supplier.

      (2) The person who receives the material will check the

physician's written request to confirm that the material received is what was ordered.

3. For deliveries during normal working hours, the RSO will tell carriers to deliver radioactive packages directly to a specified area.

4. For deliveries during off-duty hours, the RSO will tell security personnel or other designated persons to accept delivery of radioactive packages in accordance with procedures outlined in the sample memorandum below.

Sample Memorandum

MEMO TO: Chief of Security
FROM: Radiation Safety Officer
SUBJECT: Receipt of Packages Containing Radioactive Material

The security guard on duty shall accept delivery of packages containing radioactive material that arrive during other than normal working hours. Packages should be placed on a cart or wheelchair and taken immediately to the Nuclear Medicine Department, Room ____. Unlock the door, place the package on top of the counter, and relock the door.

If the package appears to be damaged, immediately contact one of the individuals identified below. Ask the carrier to remain at the hospital until it can be determined that neither the driver nor the delivery vehicle is contaminated.

If you have any questions concerning this memorandum, please call our hospital Radiation Safety Officer, _____, at extension _____.

	Name	Home Telephone
Radiation Safety Officer:		
Chief of Nuclear Medicine:		
Chief Nuclear Medicine Technologist:		
Nuclear Medicine Technologist on call (call page operator at extension _____)		
Nuclear Medicine Physician on call (call page operator at extension _____)		

APPENDIX L

Model Procedure for Safely Opening Packages Containing Radioactive Material

You may use the following model procedure for opening packages. If you follow the model procedure, you may say on your application, "We will establish and implement the model procedure for opening packages that was published in Appendix L to Medical Programs Licensing Guide Revised March 2008."

If you develop your own package opening procedure for review, you should consider for inclusion all the features in the model. Say on your application, "We have developed a package opening procedure for your review that is appended as ATT 14.7," and append your package opening procedure.

MODEL PROCEDURE

1. For packages received under the specific license, the following procedure for opening each package will be followed:

    a. Put on gloves to prevent hand contamination.

    b. Visually inspect the package for any sign of damage (e.g., wet or crushed). If damage is noted, stop the procedure and notify the Radiation Safety Officer (RSO).

    c. Measure the exposure rate from the package at 1 meter and at the package surface. If it is higher than expected, stop and notify the RSO. (The "transport index" noted on packages with "Yellow II" or "Yellow III" labels is the approximate dose rate, in millirem per hour, at 1 meter from the package surface; the surface dose rate for such packages should not exceed 200 millirem per hour. The dose rate from packages with "White I" labels should be less than 0.5 millirem per hour at the package surface.)

    d. Open the package with the following precautionary steps:

        (1) Remove the packing slip.

        (2) Open the outer package following the supplier's instructions, if provided.

        (3) Open the inner package and verify that the contents agree with the packing slip.

        (4) Check the integrity of the final source container. Look for broken seals or vials, loss of liquid, condensation, or

discoloration of the packing material.

(5) If anything is other than expected, stop and notify the RSO.

e. Wipe the external surface of the final source container and remove the wipe sample to a low-background area. Assay the wipe sample to determine if there is any removable radioactivity. (The licensee should specify in the procedure manual which instrument, for example, a thin-end-window GM survey meter, a NAI(Tl) crystal and ratemeter, a liquid scintillation counter, or a proportional flow counter, should be used for these assays. The detection efficiency must be determined to convert wipe sample counts per minute to disintegrations per minute. Note that a dose calibrator is not sufficiently sensitive for this measurement.) Take precautions against the potential spread of contamination.

f. Check the user request to ensure that the material received is the material that was ordered.

g. Monitor the packing material and the empty packages for contamination with a radiation detection survey meter before discarding.

(1) If contaminated, treat this material as radioactive waste.

(2) If not contaminated, remove or obliterate the radiation labels before discarding in in-house trash.

h. Make a record of the receipt.

3. For packages received under the general license in RHA 2.4.3 the following procedure for opening each package will be followed:

a. Visually inspect the package for any sign of damage (e.g., wet or crushed). If damage is noted, stop the procedure and notify the RSO.

b. Check to ensure that the material received is the material that was ordered.

APPENDIX M

Records of Material Use
(See RHA 4.95)

General

Many suppliers include pressure-sensitive stickers or forms that have much of the information required by the regulations. You may use these in your records and need not duplicate the information on them. Be sure to write down whatever additional information is required but is not cued or printed on them. Information does not have to be recorded in the order given in these procedures. Also, you do not have to replicate entries. For example, if you prepare a multidose vial for use one day, you do not have to record the date each time you draw a dosage from it; if you take 30 Ir-192 seeds that are each 0.5 millicuries, you do not have to list each seed individually.

M.1 Records of Unit Dosage Use

You may use the following model procedure to keep a record of unit dosage use. If you will follow the model procedure, you may say on your application, "We will establish and implement the model procedure for a unit dosage record system that was published in Appendix M.1 to Medical Programs Licensing Guide Revised March 2008."

If you prefer, you may develop your own unit dosage record system for review. If you do so, you should consider for inclusion all the features in the model procedure and carefully review the requirements of RHA 4.8.4. Say on your application, "We have developed a procedure for a unit dosage record system for your review that is appended as ATT 14.8," and append your unit dosage record procedure.

MODEL PROCEDURE

For each unit dosage received from a supplier, make a record of the:

1. Radiopharmaceutical;

2. The patient's or human research subject's name, or identification number if one has been assigned;

3. The prescribed dosage, the determined dosage, or a notation that the total activity is less than 1.1MBq (30 uCi);

4. The date and time of the dosage determination; and

5. The name of the individual who determined the dosage.

M.3 Measuring and Recording Molybdenum Concentration (RHA 4.38 and 4.101)

The regulations require that each licensee who uses a technetium generator to prepare radiopharmaceuticals must test each elution or extraction for its molybdenum concentration. (This does not have to be done when using radiopharmaceuticals obtained from a distributor.) This measurement is usually made with a dose calibrator. Licensees may not administer radiopharmaceuticals that contain more than 0.15 microcurie of Mo-99 per millicurie of Tc-99m at the time of administration. If an elution or extraction has a higher concentration, there may be a manufacturing defect that should be reported.

The model procedure for measuring molybdenum concentration is based on the use of a "molybdenum breakthrough pig." Your dose calibrator manufacturer will usually supply, as an option, a molybdenum breakthrough pig made of lead. The pig is usually thick enough to shield all the technetium photons but only a fraction of the molybdenum photons. The manufacturer will specify the Mo-99 correction factor to convert from measured Mo-99 to total Mo-99.

The following model procedure may be used to measure the molybdenum concentration in Mo-99/Tc-99m generator elution. If you will follow the model procedure, you may say on your application, "We will establish and implement the model procedure for measuring and recording molybdenum concentration that was published in Appendix M.3 to Medical Programs Licensing Guide Revised March 2008."

If you prefer, you may develop your own molybdenum concentration procedure for review. If you do so, you should consider for inclusion all the features in the model procedure and carefully review the requirements of RHA 4.38. Say on your application, "We have developed a procedure for measuring and recording molybdenum concentration for your review that is appended as ATT 14.10," and append your procedure for measuring and recording molybdenum concentration.

MODEL PROCEDURE

Each time a generator is eluted, make a record of the:

1. Date the generator was received;

2. Date and time of elution;

3. Measured Mo-99 activity in microcuries;

4. Product of the measured Mo-99 activity and the correction factor noted by the molybdenum breakthrough pig manufacturer;

5. Measured Tc-99m activity in millicuries;

6. Ratio of the total Mo-99 microcuries per millicurie of Tc-99m and checkmark that the ratio is less than 0.15 microcurie of Mo-99 per millicurie of Tc-99m. (If it isn't, stop and notify the RSO. The licensee must notify the Department if a leaking generator is detected.)

7. Initials of the person who made the record.

M.4 Keeping an Inventory of Implant Sources (RHA 4.29 and 4.96)

You may use the following model procedure to keep an inventory and use record for implant sources. If you will follow the model procedure, you may say on your application, "We will establish and implement the model procedure for keeping an inventory of implant sources that was published in Appendix M.4 to Medical Programs Licensing Guide Revised March 2008."

If you prefer, you may develop your own procedure for keeping an inventory and use record for implant sources. If you do so, you should consider for inclusion all the features in the model system and carefully review the requirements of RHA 4.29 and RHA 4.96. Say on your application, "We have developed a procedure for keeping an inventory of implant sources for your review that is appended as ATT 14.11," and append your procedure for keeping an inventory and use record for implant sources.

MODEL PROCEDURE

1. Use a locking installed cabinet or safe to store all implant sources.

2. Make a list of names of those individuals you allow to handle implant sources and have them initial beside their names.

3. For long-lived sources, draw a map of the storage drawer and indicate

the activity of the source at each storage point. For short-lived sources that you store in the manufacturer's shipping container, indicate the area in the safe where you put the container. Also, be sure to add the sources to the inventory log.

4. Post the map and the list of individuals whom you permit to handle the sources in the storage area or on the inventory log.

5. Each time you remove a source, make a record of the number and activity of sources removed, the room number of use or patient's name, and the time and date they were removed from storage; initial the record.

6. Each time you return sources to storage, immediately count them to ensure that every source removed has been returned. Then make a record of the number and activity of sources returned, the room number of use or patient's name, and the time and date they were returned to storage; initial the record.

7. If you ever perceive a discrepancy between the record and the number of sources in use and in storage, notify the RSO immediately.

APPENDIX N

Model Procedure for Area Surveys
(See RHA 4.31 and 4.97)

You may use the following model procedure to perform area surveys. If you follow the model procedure, you may say on your application, "We will establish and implement the model procedure for area surveys that was published in Appendix N to Medical Programs Licensing Guide Revised March 2008."

You may develop your own procedure for review. If you do so, you should consider for inclusion all the features in the model procedure and carefully review the requirements of RHA 4.31 and 4.97. Say on your application, "We have developed survey procedures for your review that are appended as ATT 14.12," and append your survey procedures.

MODEL PROCEDURES

Ambient Dose Rate Surveys

1. Survey Areas

   a. In radiopharmaceutical elution, preparation, and administration areas, survey at the end of each day of use with a radiation detection survey meter. If diagnostic administrations are occasionally made in patients' rooms and special care is taken to remove all paraphernalia, those rooms need not be surveyed.

   b. In laboratory areas where only small quantities of gamma-emitting radioactive material are processed (less than 200 microcuries at a time), survey monthly with a radiation detection survey meter.

   c. In radiopharmaceutical storage and radiopharmaceutical waste storage areas, survey weekly with a radiation detection survey meter.

   d. In sealed source and brachytherapy storage areas, survey quarterly with a radiation measurement survey meter.

2. Immediately notify the RSO if you find unexpectedly high or low levels.

Removable Contamination Surveys

1. Survey Areas

   a. In radiopharmaceutical elution, preparation, and administration

areas, survey for removable contamination. If diagnostic administrations are occasionally made in patients' rooms and special care is taken to remove all paraphernalia, those rooms need not be surveyed.

b. In laboratory areas where only small quantities of photon-emitting radioactive material are processed (less than 200 microcuries at a time), survey monthly for removable contamination.

c. In radiopharmaceutical storage and radiopharmaceutical waste storage areas, survey weekly for removable contamination.

2. The wipe sample assay procedure should be sufficiently sensitive to detect the presence of 2000 dpm/100 cm^2 of removable contamination (200 dpm/100cm^2 for isotopes of iodine). You must use a radioactive source with a known amount of activity to convert sample measurements (usually in counts per minute or cpm) to disintegrations per minute or dpm.

3. Immediately notify the RSO if you find unexpectedly high levels.

Records

1. Keep a record of dose rate and contamination survey results. It must include the following information:

   a. The date, area surveyed, and equipment used.

   b. The name or initials of the person who made the survey.

   c. A drawing of the areas surveyed with contamination and dose rate action levels as established by the RSO.

   d. Measured dose rates in mR/hr or contamination levels in dpm/100 cm^2, as appropriate.

   e. Actions taken in the case of excessive dose rates or contamination and follow-up survey information.

2. The RSO will review and initial the record at least monthly and also promptly in those cases in which action levels were exceeded.

The following information is not part of the model procedure.

Table N-1

Recommended Action Levels for Ambient Dose Rate Surveys

Type of Survey	Area Surveyed	Trigger Level
Ambient Dose Rate	Unrestricted	0.1 mR/hr
Ambient Dose Rate	Restricted	5.0 mR/hr

Recommended Action Levels in dpm/100cm^2 for Surface Contamination by Radiopharmaceuticals

	P-32, Co-58, Fe-59 Co-60, Se-75, Sr-85 In-111, I-123, I-125 I-131, Yb-169, Au-198	Cr-51, Co-57 Ga-67, Tc-99m Hg-197, Tl-201
1. Unrestricted areas, personal clothing	200	2,000
2. Restricted areas, protective clothing used only in restricted areas, skin	2,000	20,000

APPENDIX O

Model Procedure for Radiation Safety During Iodine Therapy Requiring Patient Hospitalization
(See RHA 4.42 and RHA 4.32)

In order to determine the release status of a patient, please refer to the Department's Regulatory Guide entitled "Release of Patients Administered Radioactive Materials" dated February 2006.
You may use the following procedure for reducing worker and public doses during radiopharmaceutical therapy and patient hospitalization. If you will follow the model procedure, you may say on your application, "We will establish and implement the model published in Appendix O to Medical Programs Licensing Guide Revised March 2008."

If you prefer, you may develop your own procedure for review. If you do so, you should consider for inclusion all the features in the model procedure and carefully review the requirements of RHA 4.42 and RHA 4.32. Say on your application, "We have developed a procedure for radiation safety during therapeutic use of radiopharmaceuticals for your review that is appended as ATT 14.14," and append your procedure.

MODEL PROCEDURE

1. The patient's room will be as far away from the nursing station and heavy traffic hallways as is consistent with good medical care. It will be a private room with private sanitary facilities and should be without carpet.

2. Prepare the room for the procedure as follows:

    a. Use leak-proof absorbent paper to cover large surfaces (the bed, chairs, and the floor around the toilet) that are likely to be contaminated. Small items (telephone, door knobs, bed remote control, television control, and nurse call cord) may be covered with absorbent paper or plastic bags.

    b. Prepare separate boxes for linen, disposable waste, and nondisposable contaminated items. Place a single large reclosable plastic bag in each box, or supply several small plastic bags.

    c. Determine whether urine will be discarded by release to the sanitary sewer or collected. If urine will be collected, prepare collection containers.

        (1) Containers should be unbreakable and closable.

(2) If there is no need for assay or volumetric determination and urine will be decayed in storage, add to each container an absorbent such as vermiculite.

(3) To avoid room contamination in the case of a spill, place containers in a box or deep tray that has been lined with a plastic bag and absorbent paper or vermiculite.

(4) Supply a few half-value layers of shielding for each container. (For I-131, one half-value layer is approximately 3 mm of lead.)

(5) Supply a wide-mouth antisplash funnel.

d. Stock additional disposable gloves, absorbent paper, and radioactive waste labels in the room for use as necessary by nursing, nuclear medicine, and radiation safety personnel.

3. Order disposable table service for the duration of the patient's stay. Inform the Housekeeping Office that personnel should stay out of the room until otherwise notified.

4. Supply the nurses with film badges, TLDs, or pocket ionization chambers.

5. Brief the nurses on radiation safety precautions. Use the sample form, "Nursing instructions for Patients Treated with Iodine-131, Phosphorus-32, or Gold-198", or your own nursing instruction form as an outline. Allow time for questions and answers during the briefing. Leave a written copy of the radiation safety precautions in the patient's chart or at the nurses' station.

6. Brief the patient on radiation safety procedures for the dosage administration, visitor control, urine collection, radioactive waste, and other items as applicable.

7. Only those persons needed for medical, safety, or training purposes should be present during the administration.

8. Mark a visitors' "safe line" on the floor with tape as far from the patient as possible.

9. Following administration of the dosage, measure the exposure rate in mR/hr at bedside, at 1 meter from bedside, at the visitors' "safe line," and in the surrounding hallways and rooms. Record this and any other necessary information on the nursing instructions form or the nurses' dosimeter signout form. Post the room with a "Radioactive Materials" sign.

10. For patients treated with liquid or gelatin-capsuled I-131, 1 day after the dosage administration, measure the thyroid burden of all personnel who were present for the administration. Also consider a thyroid burden

assay for patient care personnel 2 days after the administration. Make a record of the worker's name, amount of I-131 activity in a thyroid phantom in microcuries and associated counts per minute, the counts per minute from the worker's thyroid, the calculated thyroid burden, and date.

11. As the therapy proceeds, pick up waste for transfer to a decay-in-storage or decontamination area.

12. Do not release any patient until the requirements of RHA 4.32 can be met. To determine this status, refer to the Department’s Guide “Release of Patients Administered Radioactive Materials” dated February 2006. If you use the exposure rate standard as the release criterion, measure it with a radiation measurement survey meter at a distance of 1 meter from the umbilicus while the patient is standing or, if the patient is not ambulatory, 1 meter from the bedside with the patient supine.

13. Before using the room for general occupancy, it must be decontaminated and released to the Admitting Office.

    a. Remove all absorbent paper, and place it in the appropriate container.

    b. Transfer all containers to a decay-in-storage or decontamination area.

    c. Use a radiation detection survey meter to check for room contamination. Clean contaminated areas until removable contamination is less than 200 dpm/100cm^2.

    d. Call the Housekeeping Office to remove the cleaning restriction and call the Admitting Office to return the room to the vacant list.

APPENDIX P

Model Procedure for Radiation Safety During Implant Therapy Requiring Patient Hospitalization
(See RHA 4.32, 4.47, RHA 4.48, 4.49, and 4.50)

In order to determine the release status of a patient, please refer to the Department's Regulatory Guide entitled "Release of Patients Administered Radioactive Materials" dated February 2006.
You may use the following procedure to reduce worker and public dose during implant therapy. If you will follow the model procedure, you may say on your application, "We will establish and implement the model procedure for radiation safety during implant therapy that was published in Appendix P to Medical Programs Licensing Guide Revised March 2008."

If you prefer, you may develop your own procedure for review. If you do so, you should consider for inclusion all the features in the model procedure and carefully review the requirements of RHA 4.32, 4.47, RHA 4.48, 4.49, and 4.50. Say on your application, "We have developed a procedure for radiation safety during implant therapy for your review that is appended as ATT 14.15," and append your procedure.

MODEL PROCEDURE

1. The patient's room will be as far away from the nursing station and heavy traffic hallways as is consistent with good medical care. It will be a private room unless the dose at one meter from the implant meets the requirements in RHA 3.13.1.

2. Supply the nurses with film badges, TLDs, or pocket ionization chambers.

3. Brief the nurses on radiation safety precautions. Use the sample form, "Nursing Instructions for Patients Treated with Temporary Implant Sources," or your own nursing instruction form as an outline. Allow time for questions and answers during the briefing.

4. Brief the patient on radiation safety procedures for confinement to bed, visitor control, and other items as applicable consistent with good medical care.

5. Only those persons needed for medical, safety, or training purposes should be present during the implant procedure.

6. Mark a visitors' "safe line" on the floor with tape as far from the patient as possible.

7. Following the implant, measure the exposure rate in mR/hr at bedside, at 1 meter from bedside, at the visitors' "safe line," and in the surrounding hallways and rooms (the last rates must conform to requirements in RHA 3.13.1. Record this and any other necessary information on the nursing instruction form or the nurses' dosimeter signout form. Post the room with a "Radioactive Materials" sign.

8. Do not release any patient who has received a temporary implant from the hospital until both a radiation survey of the patient and a count of implant sources, trains, or ribbons confirm that all sources have been removed from the patient and are accounted for. Perform this check immediately after the removal of the sources. Keep a record confirming the source count and radiation survey on the implant source running inventory form. For low-activity seeds (less than 1 millicurie), use an individual seed to check the survey meter to be sure it will easily detect a seed that has not been removed or has been lost.

9. Do not release any patient who has received a permanent implant from the hospital unless the requirements of RHA 4.32 can be met. If following exposure rate criteria found in the Patient Release Guide, measure this exposure rate with a radiation measurement survey meter at a distance of 1 meter from the umbilicus with the patient standing.

APPENDIX Q

Model Procedures for Developing, Maintaining and Implementing Written Directives
(See RHA 4.17)

Each applicant or licensee under this part, as applicable, shall establish and maintain a written directive program to provide high confidence that radioactive material or radiation from radioactive material will be administered as directed by an authorized user.

You may use the following procedure to establish and maintain a written directive program. If you will follow the model procedure, you may say on your application, "We will establish and implement the model procedures for quality management programs that were published in Appendix R to Medical Programs Licensing Guide Revised March 2008."

The written directive program must include written policies and procedures to meet the following specific objectives:

A. That, prior to administration, a written directive[1] is prepared for:

1. Any teletherapy radiation dose;

2. Any gamma stereotactic radiosurgery radiation dose;

3. Any brachytherapy radiation dose;

4. Any administration of quantities greater than 30 microcuries of either sodium iodide I-125 or I-131;

5. Any therapeutic administration of a radiopharmaceutical, other than sodium iodide I-125 or I-131.

[1] If, because of the patient's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive will be acceptable, provided that the oral revision is documented as soon as possible in the patient's record and a revised written directive is signed by the authorized user within 48 hours of the oral revision.

Also, a written revision to an existing written directive may be made for any diagnostic or therapeutic procedure provided that the revision is dated and signed by an authorized user prior to the administration of the radiopharmaceutical dosage, the brachytherapy dose, the gamma stereotactic radiosurgery dose, the teletherapy dose, or the next teletherapy fractional dose.

If, because of the emergent nature of the patient's condition, a delay in order to provide a written directive would jeopardize the patient's health, an oral directive will be acceptable, provided that the information contained in the oral directive is documented immediately in the patient's record and a written directive is prepared within 24 hours of the oral directive.

B. That, prior to each administration, the patient's identity is verified as the individual named in the written directive;

C. That final plans of treatment and related calculations for brachytherapy, teletherapy, and gamma stereotactic radiosurgery are in accordance with the respective written directives;

D. That each administration is in accordance with the written directive; and

E. That any unintended deviation from the written directive is identified and evaluated, and appropriate action is taken.

MODEL PROCEDURES FOR SEALED THERAPEUTIC SOURCES AND DEVICES CONTAINING SEALED THERAPEUTIC SOURCES

We will establish the additional following procedures:

A. To ensure that the dose is delivered in accordance with the written directive, the authorized user must approve a treatment plan that provides sufficient information and direction to meet the objectives of the written directive. Suggested guidelines for information to be included in the treatment plan may be obtained from the American College of Radiology.

B. For sealed sources inserted into the patient's body, radiographs or other comparable images (e.g., computerized tomography) will be used as the basis for verifying the position of the nonradioactive dummy sources and calculating the administered dose before administration; however, some brachytherapy procedures may require the use of various fixed geometry applicators (e.g., appliances or templates) to establish the location of the temporary sources and calculate the exposure time (or, equivalently, the total dose) required to administer the prescribed brachytherapy treatment. In these cases, radiographs or other comparable images may not be necessary, provided the position of the sources is known prior to insertion of the radioactive sources and calculation of the exposure time (or, equivalently, the total dose).

C. Dose calculations will be checked before administering the prescribed therapy dose. An authorized user or a qualified person under the supervision of an authorized user (e.g., an authorized medical physicist, oncology physician, dosimetrist, or radiation therapist), preferably one who did not make the original calculations, will check the dose calculations. The responsibilities and conditions of supervision are contained in RHA 4.15. Suggested methods for checking the calculations include the following:

1 . Computer-generated dose calculations will be checked by examining the computer printout to verify that correct input data for the patient were used in the calculations (e.g., source strength and positions).

2. The computer-generated dose calculations for input into the therapy console will be checked to verify correct transfer of data from the computer (e.g., channel numbers, source positions, and treatment times).

3. Manual dose calculations will be checked for:

   a. Arithmetic errors,

   b. Appropriate transfer of data from the written directive, treatment plan, tables and graphs,

   c. Appropriate use of nomograms (when applicable), and

   d. Appropriate use of all pertinent data in the calculations

If possible, the therapy dose will be manually calculated to a single key point and the results compared to the computer-generated dose calculations. If the manual dose calculations are performed using computer-generated outputs (or vice versa), particular emphasis should be placed on verifying the correct output from one type of calculation (e.g., computer) to be used as an input in another type of calculation (e.g., manual). Parameters such as the transmission factors for wedges and applicators and the source strength of the sealed source used in the dose calculations should be checked.

D. After insertion of permanent implant brachytherapy sources, we will have an authorized user promptly record the actual number of radioactive sources implanted and sign or initial the patient's chart or other appropriate record.

E. Acceptance testing will be performed by a qualified person (e.g., an authorized medical physicist)on each treatment planning or dose calculating computer program that could be used for dose calculations. Acceptance testing shall be performed before the first use of a treatment planning or dose calculating computer program for therapy dose calculations. Each treatment planning or dose calculating computer program will be assessed based on our specific needs and applications. Acceptance testing will also be considered after each source replacement or when spot-check measurements indicated that the source output differed by measurements more than 5% from the output obtained at the last full calibration corrected mathematically for radioactive decay.

F. Independent checks on full calibration measurements will be performed when possible. The independent check will include an output measurement for a single specified set of exposure conditions and will be performed within 30 days following the full calibration measurements. The

independent check will be performed by either:

1. An individual who did not perform the full calibration using a dosimetry system other than the one that was used during the full calibration (the dosimetry system will meet the requirements specified in RHA 4.63), or

2. An authorized medical physicist (or an oncology physician, dosimetrist, or radiation therapist who has been properly instructed) using a thermoluminescence dosimetry service available by mail that is designed for confirming therapy doses and that is accurate within 5%.

G. Full calibration measurements will include the determination of transmission factors for trays, wedges, applicators, etc. Transmission factors for other beam-modifying devices (e.g., nonrecastable blocks , recastable block material, bolus and compensator materials, and split beam blocking devices) will be determined before the first medical use of the beammodifying device and after replacement of the source.

H. For GSR, particular emphasis will be directed toward verifying that the stereoscopic frame coordinates on the patient's skull match those of the treatment plan.

I. A physical measurement of the teletherapy output will be made under applicable conditions prior to administration of the first teletherapy fractional dose, if the patient's treatment plan includes (1) field sizes or treatment distances that fall outside the range of those measured in the most recent full calibration or (2) transmission factors for beam-modifying devices (except nonrecastable and recastable blocks, bolus and compensator materials, and split-beam blocking devices) not measured in the most recent full calibration measurement.

J. If possible, a weekly chart check will be performed by a qualified person under the supervision of an authorized user (e.g., an authorized medical physicist, dosimetrist, oncology physician, or radiation therapist) to detect mistakes (e.g., arithmetic errors, miscalculations, or incorrect transfer of data) that may have occurred in the daily and cumulative dose administrations from all treatment fields or in connection with any changes in the written directive or treatment plan.

MODEL PROCEDURES FOR ANY THERAPEUTIC DOSE OR DOSAGE OF A RADIONUCLIDE OR ANY DOSAGE OF QUANTITIES GREATER THAN 30 MICROCURIES OF SODIUM IODINE I-131

We will establish the following procedures:

A. An authorized user must prepare, date, and sign a written directive prior to the administration of any dose or dosage.

B. Prior to administering a dose or dosage, the patient's identity will be

positively verified as the individual named in the written directive. Examples of patient identity verification include the patient's ID bracelet, hospital ID card, driver's license or social security card.

C. Before administering the dose or dosage, the specific details of the administration will be verified in accordance with the written directive or treatment plan. All components of the written directive (radionuclide,total dose or dosage, etc.) will be confirmed by the person administering the dose or dosage to verify agreement with the written directive. Appropriate verification methods include: measuring the activity in the dose calibrator, checking the serial number of the sealed sources behind an appropriate shield, using color-coded vials or sealed sources, or using clearly marked storage locations. The verification will be performed by at least one qualified person (e.g., an oncology physician, authorized medical physicist, nuclear medicine technologist, or radiation therapist) preferably other than the individual who prepared the dose or dosage or the treatment plan.

D. All workers will be instructed to seek guidance if they do not understand how to carry out the written directive. Specifically, workers should ask if they have any questions about what to do or how it should be done, prior to administration, rather than continuing a procedure when there is any doubt.

Model Procedure for Retaining Written Directives

The licensee will retain:

A. Each written directive; and

B. A record of each administered radiation dose or radiopharmaceutical dosage where a written directive is required, in an auditable form, for three years after the date of administration.

C. The licensee may make modifications to the written directive program to increase the program’s efficiency provided the program’s effectiveness is not decreased. The licensee shall furnish the modification to the Department within 30 days after modification has been done.

D. Each applicant for new license, as applicable, shall submit to the Department a written directive program as part of the application for a license and implement the program upon issuance of the license by the Department.

APPENDIX R

Model Procedure for Waste Disposal
(See RHA 4.34, RHA 3.27 and RHA 3.29)

The following general guidance and procedure may be used for disposal of radioactive waste. If you follow all the general guidance and procedures, you may say on your application, "We will establish and implement the general guidance and model procedures for waste disposal that were published in Appendix R to Medical Programs Licensing guide Revised March 2008."

If you prefer, you may develop your own procedure for review. If you do so, you should consider for inclusion all the features in the general guidance and models and carefully review the requirements of RHA 4.34, RHA 3.27 and RHA 3.29. Say on your application, "We have developed a procedure for waste disposal for your review that is appended as ATT 15.1," and attach your procedure.

Overview

There are four commonly used methods of waste disposal: release to the environment through the sanitary sewer or by evaporative release; decay-in-storage (DIS); transfer to a burial site or back to the manufacturer; and release to in-house waste. With the exception of the patient excreta and generally licensed in vitro kit exemptions, nothing in these guidelines relieves the licensee from maintaining records of the disposal of licensed material.

General Guidance

1. All radioactivity labels must be defaced or removed from containers and packages prior to disposal in in-house waste. If waste is compacted, all labels that are visible in the compacted mass must be defaced or removed.

2. Remind employees that nonradioactive waste such as leftover reagents, boxes, and packing material should not be mixed with radioactive waste.

3. Occasionally monitor all procedures to ensure that radioactive waste is not created unnecessarily. Review all new procedures to ensure that waste is handled in a manner consistent with established procedures.

4. In all cases, consider the entire impact of various available disposal routes. Consider occupational and public exposure to radiation, other hazards associated with the material and routes of disposal (e.g., toxicity, carcinogenicity, pathogenicity, flammability), and expense.

MODEL PROCEDURE FOR DISPOSAL OF LIQUIDS AND GASES

Liquids may be disposed of by release to the sanitary sewer or evaporative release to the atmosphere. This does not release licensees from complying with other regulations regarding toxic or hazardous properties of these materials.

1. Regulations for disposal in the sanitary sewer appear in RHA 3.29. Material must be readily soluble or dispersible in the water. There are daily and monthly limits based on the total sanitary sewerage release of your facility. (Excreta from patients undergoing medical diagnosis or therapy is exempt from all the above limitations; see paragraph RHA 3.29.2. Make a record of the date, radionuclide, estimated activity that was released (in millicuries or microcuries), and of the sink or toilet at which the material was released.

2. Limits on permissible concentrations in effluents to unrestricted areas are enumerated in RHA 3.53, Table 2 of Appendix B to Department Regulation 61-63. These limits apply at the boundary of the restricted area. Make a record of the date, radionuclide, estimated activity that was released (in millicuries or microcuries), and of the sink or toilet at which the material was released.

3. Liquid scintillation-counting media containing 0.05 microcurie per gram of H-3 or C-14 may be disposed of without regard to its radioactivity (RHA 3.31). Make a record of the date, radionuclide, estimated activity (in millicuries or microcuries), calculated concentration in microcuries per gram, and how the material was disposed of.

MODEL PROCEDURE FOR DISPOSAL BY DECAY-IN-STORAGE (DIS)

Short-lived material (physical half-life less than 65 days) may be disposed of by DIS. If you use this procedure, keep material separated according to half-life.

1. Consider using separate containers for different types of waste, e.g., capped needles and syringes in one container, other injection paraphernalia such as swabs and gauze in another, and unused dosages in a third container. Smaller departments may find it easier to use just one container for all DIS waste. Because the waste will be surveyed with all shielding removed, the containers in which waste will be disposed of must not provide any radiation shielding for the material.

2. When the container is full, seal it with string or tape and attach an

identification tag that includes the date sealed, the longest-lived radioisotope in the container, and the initials of the person sealing the container. The container may then be transferred to the DIS area.

3. Decay the material for at least 10 half-lives.

4. Prior to disposal as in-house waste, monitor each container as follows:

   a. Check your radiation detection survey meter for proper operation;

   b. Plan to monitor in a low-level (less than 0.05 millirem per hour) area;

   c. Remove any shielding from around the container;

   d. Monitor all surfaces of each individual container;

   e. Discard as in-house waste only those containers that cannot be distinguished from background. Record the date on which the container was sealed, the disposal date, and type of material (e.g., paraphernalia, unused dosages). Check to be sure no radiation levels are visible.

   f. Containers that can be distinguished from background radiation levels must be returned to the storage area for further decay or transferred for burial.

5. If possible, Mo-99/Tc-99m generators should be held 60 days before being dismantled because of the occasional presence of a long-lived contaminant. When dismantling generators, keep a radiation detection survey meter (preferably with a speaker) at the work area. Dismantle the oldest generator first, then work forward chronologically. Hold each individual column in contact with the radiation detection survey meter in a low-background (less than 0.05 mR/hr) area. Log the generator date and disposal date for your waste disposal records. Remove or deface the radiation labels on the generator shield.

MODEL PROCEDURE FOR TRANSFER FOR BURIAL

Except for material suitable for DIS and some animal carcasses, solids must be transferred to a burial site. Follow the packaging instructions you received from the transfer agent and the burial site operator. For your record of disposal, keep the consignment sheet that the transfer agent gave you.

MODEL PROCEDURE FOR RELEASE TO IN-HOUSE WASTE

Waste from in-vitro kits that are generally licensed pursuant to

RHA 2.4.3 is exempt from waste disposal regulations. Radioactive labels should be defaced or removed. There is no need to keep any record of release or make any measurement.

R-3

MODEL PROCEDURE FOR RETURNING GENERATORS TO THE MANUFACTURER

Used Mo-99/Tc-99m generators may be returned to the manufacturer. This permission does not relieve licensees from the requirement to comply with 10 CFR Part 71 and Department of Transportation (DOT)regulations.

1. Retain the records needed to demonstrate that the package qualifies as a DOT Specification 7A container (see DOT regulations, paragraph 173.415(a) of 49 CFR Part 173).

2. Assemble the package in accordance with the manufacturer's instructions.

3. Perform the dose rate and removable contamination measurements required by paragraph 173.475(i) of 49 CFR Part 173.

4. Label the package and complete the shipping papers in accordance with the manufacturer's instructions.

APPENDIX S

Considerations in Making Radiation Safety Program Changes
(See RHA 4.14)

The regulations allow the licensee to make changes that are not potentially important to safety in radiation safety procedures and in equipment. When making changes, it is the licensee's responsibility to ensure that the result will be in accord with the regulations and license conditions. Any change must be reviewed for radiation safety considerations before it is approved.

You should consider the following before making an application for a license amendment or making changes. Not all the questions apply to all changes. There may be other questions you should consider before making changes.

General

1. Proposed changes should be fully explained.
2. Do not include unexplained acronyms, abbreviations, or undefined words.
3. Spell out measurement units such as millicurie, microcurie, and millirem per hour; use the abbreviations only in calculations or log sheets.
4. Identify, by name or office, who is responsible for doing each task.

Room Changes

1. Why is the change needed?
2. What materials, and how much of each, will be used in the room?
3. Can the room be secured in case of spills?
4. Can the room surfaces be cleaned?
5. Is the room adequately ventilated?
6. Does the room provide radiation shielding?
7. What are the anticipated doses each week in the room and in surrounding areas?
8. What are surrounding areas used for? What might they be used for in the future?
9. Can the old room be cleaned, surveyed, and released for unrestricted use?

Equipment Changes

1. Why is the change needed?

2. Was the equipment designed for the intended purpose?

3. For detection and measuring equipment:

   a. What is the lowest level of detection for the equipment?

   b. What is the level of detection required?

   c. Will the instrument be compromised by ambient radiations, light, temperature, humidity, or chemicals in the area?

   d. In case it fails, is backup equipment available, and can it be repaired in a timely fashion?

4. For protection equipment:

   a. What level of protection does it provide?

   b. What is the required level of protection?

   c. In case it fails, is backup equipment available, and can it be repaired in a timely fashion?

Procedure Changes

1. Why is the change needed?
2. What doses or dose rates apply to the individuals affected by the changes?
3. For each step in the procedure, what things are likely to go wrong either because of equipment failure or human error?
4. What are the likely consequences of problems noted in Question 3?
5. What steps can be taken to mitigate the consequences noted in Question 4?

APPENDIX T

Recommended Support Equipment and Services

Depending on the type of use and the size of the program, you will need various types of equipment and services to support your radiation safety program. The suggested list provided here does not include the many disposable or reusable items that are also necessary. Also, the list is not all-inclusive, and all items are not absolutely necessary.

For RHA 4.35

1. Radiation detection survey meter
2. Dose calibrator
3. Constancy check source
4. Sealed sources for dose calibrator accuracy test
5. Constancy check source for uptake, dilution, and excretion equipment
6. Leak-test service for sealed sources
7. Syringe shield
8. Personnel monitoring service
9. Survey meter calibration source
10. Vial shields
11. Personnel shields

For RHA 4.37

1. Radiation detection survey meter
2. Radiation measurement survey meter
3. Dose calibrator
4. Constancy check source
5. Sealed sources for dose calibrator accuracy test
6. Leak-test service for sealed sources
7. Syringe shield
8. Hot lab area monitor
9. Flood source for gamma cameras
10. PLES, bar, orthogonal-hole, or quadrant phantom for gamma cameras
11. Lead L-block
12. Fume hood
13. Radioactive aerosol and gas administration system and trap
14. Personnel monitoring service
15. Survey meter calibration service
16. Vial shields
17. Personnel shields

For RHA 4.40

1. Radiation detection survey meter
2. Radiation measurement survey meter
3. Dose calibrator
4. Constancy check source
5. Sealed sources for dose calibrator accuracy test
6. Leak-test service for sealed sources

7. Syringe shield
8. Fume hood
9. Personnel monitoring service
10. Survey meter calibration service
11. Vial shields
12. Personnel shields

For RHA 4.46

1. Radiation detection survey meter
2. Radiation measurement survey meter
3. Lead L-block
4. Remote handling tools
5. Shielded transport cart
6. Shielded storage safe
7. Leak-test service for sealed sources
8. Personnel monitoring service
9. Survey meter calibration service
10. Personnel shields

Note: If you are authorized for only a Sr-90 ophthalmic applicator, only a storage safe or built-in locked storage cabinet and leak-test service are necessary.

For RHA 4.56

1. Secure storage area
2. Leak-test service for sealed sources
3. Radiation monitoring service for measuring dose rates from packages with replacement sources and decayed sources.

For RHA 4.58

1. Radiation measurement or radiation detection survey meter
2. Room monitor
3. Patient viewing system
4. Leak-test service
5. Calibrated dosimetry system
6. Spot-check dosimetry system
7. Direct-reading pocket dosimeters
8. Personnel monitoring service
9. Teletherapy physicist service
10. Survey meter calibration service

Descriptions

A radiation detection survey meter usually has a GM tube or NaI(Tl) crystal detector. The scale may be labeled in cpm or mR/hr. It is useful for detecting microcurie amounts of radioactivity and indicating approximate exposure levels. If it is calibrated in mR/hr, the most sensitive scale will probably have a full-scale deflection between 0.1 and 1.0 mR/hr. It can be used for measuring small amounts of radioactivity if the user has measured its detection efficiency (cpm/dpm) for the radionuclide being measured.

A radiation measurement survey meter can actually measure mR/hr. The detector is an ionization chamber, which is usually larger than a GM tube. The scale is labeled in mR/hr, and the most sensitive scale usually will have a full-scale deflection between 1 and 10 mR/hr.

The dose calibrator uses an ionization chamber or GM detectors to determine the amount of radiation given off by a syringe or vial containing radioactive material. The logic system within the calibrator can then calculate the amount of radioactivity in the sample. Most dose calibrators have a digital display with either a "select range" switch or an automatic range-switching circuit. The final display is in microcuries, millicuries, or curies. A dose calibrator can measure from a few microcuries to a few curies. It is not sensitive enough to measure contamination wipe results.

A constancy check source is a sealed source with the date of manufacturer, radioisotope, and approximate activity noted.

A dedicated check source is a long-lived radioactive source used to check the day-to-day constancy of an instrument. The same source a "dedicated" source) must be used every day so that the user knows what reading to expect from the instrument. The source may also be used for other purposes.

The sealed sources for dose calibrator accuracy are also sealed sources with the date of manufacture and radioisotope noted. However, the activity will be certified to within a few percent by the manufacturer. These need not be on hand if the dose calibrator accuracy test is done by a contract service.

The leak-test service may be done in-house or performed as a contract service. Leak-test wipes cannot be measured in a dose calibrator, and a GM survey meter may not be sensitive enough to detect contamination on a wipe sample. Usually a well-type NaI(Tl) crystal with a ratemeter is necessary to assay gamma-emitter leak-test wipes. To determine the efficiency

of detection, a sealed source with the same radioisotope as the source being tested is used, but its activity should be between 0.1 and 10 microcuries. This activity will be certified by the manufacturer to an accuracy within a few percent.

The hot lab area monitor usually has a GM detector, and the scale may be labeled in cpm or mR/hr. It should be sufficiently sensitive to detect an unshielded patient dose left lying unshielded anywhere in the hot lab.

The flood source for gamma cameras may be either one that is sealed or one that is filled by the user. The sealed sources usually contain about 5 millicuries of Co-57. The sources that can be filled by the user usually have a removable screw in a port through which radioactive material can be injected each morning.

PLES, bar, orthogonal-hole, and quadrant phantoms are used to monitor geometric linearity and resolution capability in gamma cameras. This type of test should be run weekly according to the instructions supplied by the manufacturer or the instructions in Appendix E to this guide.

A fume hood should have an adjustable sash. It should be directly vented to the outside air. The face velocity should be approximately 100 linear feet per minute with the sash at its normal location. This should be measured with a velometer. If one is not available, hang a strip of tissue paper about 1 inch wide and 3 inches long from the bottom of the sash; at the proper face velocity, it will be gently deflected into the hood.

A teletherapy room monitor usually has a GM detector and either a scale labeled in mR/hr or annunciator lights indicating when the source is on and off. It must be installed so it can be easily seen when entering the teletherapy room. A backup power supply must be provided.

When used by teletherapy technicians, direct-reading or indirect-reading pocket dosimeters provide an immediate indication of personnel whole body exposure in case of an accidental exposure. These should be calibrated using the source and procedure used for calibrating survey meters.

Personnel shields are used to shield workers from radioactive patients. They may be mobile upright shields in the nuclear medicine clinic or a patient's room when a technician or nurse must stay beside a patient, or they may be lead sheets used to shield transporters from patients in wheelchairs.

APPENDIX U

Filing System

The purpose of a filing system is to allow for the quick access of records. The system should be constructed to allow a person who is not familiar with the system to use it with minimal training. If you have not established a system, the one described below may be helpful.

The filing system described contains two parts: The first part includes Section A and 0-6 for files that are small or occasionally accessed. The second part consists of five loose leaf notebooks used to file records that are large, frequently accessed, or easily filed in alphabetical or chronological order.

Section A -- Active Projects

Set up an individual file for each project, e.g., planning a new radioisotope lab or x-ray installation or a research project. Label each file with a short title. File chronologically with new material in front. For example:

Shielding calculations for new x-ray room
TLD project
Registration and travel to summer meeting

Section O -- Forms

Set up a file for master copies of the forms you use in your facility and a file for copies of each form. Label the files as indicated.

0.1 Masters
0.2 Personal Exposure Monitor Applications
0.3 Exposure History Request
0.4 Exposure History Report
0.5 Teletherapy Monthly Check
0.6 Nuclear Medicine Daily Survey
0.7 Survey Meter Calibration
0.8 Sink Disposal Logs
0.9 Vented Release Logs
0.10 Decay-In-Storage Release Records
0.11 Room Survey Master Forms, etc.

Section 1 -- Committees

Each subsection of this section is devoted to a single committee. In some cases, the file will contain only meeting minutes. In other cases, the file may also include a committee charter, curricula vitae of members, and topical reports.

1.1 Radioactive Drug Research Committee
1.2 Hospital Safety Committee
1.3 Research Safety Committee
1.4 Research Review Committee
1.5 Radiation Safety Committee, etc.

Section 2 -- Radioactive Material License

2.1 License Applications, License
2.2 Amendment Requests, Amendments
2.3 Photocopies of License
2.4 Records of Minor Changes
2.5 Inspection Reports and Replies
2.6 Visiting Authorized User Credentials
2.7 Misadministration Reports
2.8 Other Correspondence, etc.

Section 3 -- Inventories, Surveys, and Waste

3.0 Inventory Summary Sheet
3.11 Nuclear Medicine Surveys and Inventory Summaries
3.12 Research Lab Surveys and Inventory Summaries
3.21 I-Therapy Room Release Surveys
3.22 Brachytherapy/Sealed Source Quarterly Inventory and Survey
3.23 Leak-Test Records
3.30 Room Survey Sets for Future Use
3.41 Annual Sink Disposal Summary
3.42 Annual Vent Disposal Summary
3.43 Hot Lab Sink Disposal Logs
3.44 Research Lab Sink Disposal Logs
3.45 Decay-In-Storage Release Logs, etc.

Section 4 -- Contract Services

4.1 Personal Dosimetry Service Contract
4.2 Change Forms
4.3 Monthly Exposure Reports
4.4 Waste Shipment Contract
4.5 Transfers of Radioactive Material, etc.

Section 5 -- Training Lecture Outlines, Handouts, and Attendance Logs

5.11 Nonradiology Physicians

5.12 Nonradiology Technologists
5.21 Radiology Physicians
5.22 Radiology Technologists
5.31 Administrators
5.32 Security
5.33 Physical Plant
5.34 Housekeeping
5.35 Animal Research Facility

5.41 Nursing--General Radiation Safety
5.42 Nursing for Brachytherapy
5.43 Nursing for Iodine Therapy
5.51 Brachytherapy Team
5.52 Diagnostic Nuclear Medicine Personnel
5.53 Therapeutic Nuclear Medicine Personnel
5.54 Teletherapy Personnel
5.61 In Vitro Users, etc.

Section 6 -- Radiation Safety Equipment on Hand

Set up an individual file for each piece of equipment. The file should contain the user's manual, guarantee, service reports, and calibration reports. File alphabetically by manufacturer.

Section 7 -- Incidents

7.1 Personnel Exposures
7.2 Spills or Losses with No Personnel Exposure
7.3 Procedural Incidents

Section 8 -- Facility Description

Set up files for blueprints, drawings, and permanently installed equipment such as incinerators, fume hoods, and walk-in boxes.

Loose-Leaf Notebooks

1. Dosimetry Service Monthly Packing Slips. Checkmark each name when the monitor is returned at the end of the monitor period. This will highlight persons who are not returning monitors promptly for processing.
2. Personnel Dosimetry Individual Applications. Behind each individual's application form, file copies of previous employment exposure, incidents, requests for previous employment exposure, and bioassay results.

3. Budget and Purchase Orders

4. Regulatory Guides

5. Standard Operating Procedures

6. Rules and Regulations